

EPA Jacket 35900-2

Vol.1

Decision # 359441
SUBMISSION BAR CODE # 782638

REVIEWER RD

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 35900-2 PM 33 ACTION CODE 332

DESCRIPTOR _____

☐ CHILD RESISTANT PACKAGING: ☐ CERTIFICATION
☐ NON-RESIDENTIAL USE ONLY
☐ NOT APPLICABLE

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL

PROPOSED CLASSIFICATION: ☐ GENERAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

07 15 05

07 27 05

07 28 05

~~METHOD OF SUPPORT~~

~~FORMULATORS EXEMPTION~~

☐ CITE ALL
☐ SELECTIVE
☐ NOT SUBMITTED
☐ NOT APPLICABLE
☐ INCORRECT/RESUB

☐ SUBMITTED
☐ NOT SUBMITTED
☐ NOT APPLICABLE
☐ INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #

DATE
SENT

DUE
DATE

DATE
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

RED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER _____

STATUS _____

RESPONSE CODE

17

RESPONSE DATE

08/17/05



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

AUG 17 2005

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Christina M. Swick
Agent for,
Ionics, Inc.
3039 Washington Pike
Bridgeville, PA 15017

Mail to: Lewis & Harrison
122 C Street, N.W., Suite 740
Washington, D.C. 20001


Subject: HYgene
EPA Registration Number 35900-2
Your Amendment Dated July 15th, 2005
EPA Received Date July 27th, 2005

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to update the basic Confidential Statement of Formula to include an additional production facility, is acceptable.

Your notification has been made part of the permanent record for this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,


Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

33

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

July 15, 2005

HAND DELIVERED

Office of Pesticide Programs
Antimicrobial Division
Document Processing Desk (NOTIF)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, Virginia 22202

ATTN: Marshall Swindell
Product Manager, Team 33

SUBJECT: Ionics, Inc.
HYgene Bacteriostatic Water Filter Media (EPA Reg. No. 35900-2)
Notification of Revised CSF

Dear Mr. Swindell:

As agent for Ionics, Inc., I am submitting a notification to update the basic CSF for HYgene Bacteriostatic Water Filter Media (EPA Reg. No. 35900-2). The new basic CSF includes an additional production facility. Ionics, Inc. affirms that the beginning materials, manufacturing process, preliminary analyses, and other product chemistry data remain unchanged. Accordingly, the nominal concentrations, upper, and lower certified limits for the active ingredient and all impurities are identical to those which appear on the currently approved CSF.

The following documents are enclosed to support this notification:

1. Application for Pesticide Notification (OPP ID No. 296849); and,
2. Basic Confidential Statement of Formula (CSF) dated July 15, 2005.

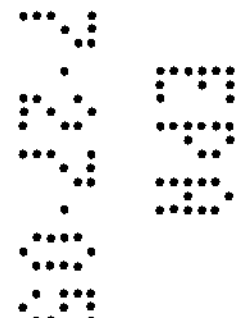
If you have any questions and/or comments, please feel free to contact me at 202-393-3903 x16 or cswick@lewisharrison.com.

Sincerely yours,

Christina M. Swick

Christina M. Swick
Agent for Ionics, Inc.

Enclosures



**EPA**

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other: Notification

OPP Identifier Number
296849

Application for Pesticide - Section I

1. Company/Product Number 35900-2	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HYgene Bacteriostatic Water Filter Media	PM# Team 33	
5. Name and Address of Applicant (Include ZIP Code) Ionics, Inc. 3039 Washington Pike Bridgeville, PA 15017 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)**Notification of Revision of CSF in Accordance With PR Notice 98-10**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: Christina M. SwickDate: 7/15/05**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other:	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label Is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Christina M. Swick, Lewis & Harrison 122 C Street NW #740, Washington DC 20001	Title Agent for Ionics, Inc.	Telephone No. (Include Area Code) 202-393-3903 (ext. 16)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <u>Christina M. Swick</u>	3. Title Agent for Ionics, Inc.	
4. Typed Name Christina M. Swick, Lewis & Harrison	5. Date July 15, 2005	



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

296849

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed label in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name		Title		Telephone No. (include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature		3. Title			
4. Typed Name		5. Date			

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2138), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, II, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-top," reregistration, etc.

- 1-5. Self-explanatory
6. EPA Use Only

DECISION PKG. NO. 356602SUBM. DUE DATE 07-21-05SUBMISSION BAR CODE # 777859REVIEWER P JenkinsCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 35900-2 PM 33 ACTION CODE 345DESCRIPTOR Formula Change FQPA NFQPA ☐ CHILD RESISTANT PACKAGING: ☐ REQUIRED ☐ NOT REQUIREDREGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

04/21/0504/22/0504/28/05

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL☐ SELECTIVE☐ SUBMITTED☐ NOT SUBMITTED☐ NOT SUBMITTED☐ N/A☐ N/A

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNEDCHEMISTRY EFFICACY ACUTE TOX. RASSB TOX. ENVIRON. FATE FISH/WILDLIFE OTHER: STATUS RESPONSE CODE 17RESPONSE DATE

JUL 05 2005 ✓

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 05 2005

Lewis & Harrison, Agent for
Ionics, Inc.
122 C Street NW, Suite 740
Washington, DC 20001

Attention: Christina M. Swick

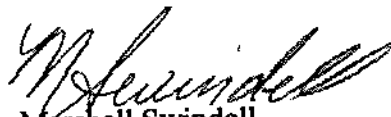
Subject: HYgiene Bacteriostatic Water Filter Media
EPA Registration No. 35900-2
Amendment Application Date: April 21, 2005
EPA Received Date: April 22, 2005

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, to add alternate sources of inert ingredient is acceptable.

The revised alternate Confidential Statement of Formula (CSF) dated April 22, 2005, is acceptable. It is in compliance with 40 CFR, Part 158.175 and PR Notice 91-2, it agrees with the label. This information has been placed in the subject product file.

If you have any questions concerning this letter, please contact me at 703-308-6341 or Portia Jenkins at (703) 308-6230.

Sincerely yours,



Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL							
SUPNAME							
DATE							

Claimed confidential by submitter

**EPA**

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number
296986

Application for Pesticide - Section I

1. Company/Product Number 35900-2	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HYgene Bacteriostatic Water Filter Media	PM# Team 33	
5. Name and Address of Applicant (Include ZIP Code) Ionics, Inc. 3039 Washington Pike Bridgeville, PA 15017 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☒ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated _____
☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application
☐ Notification - Explain below. ☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Minor Formulation Amendment to add Additional Sources of Inert Ingredient

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Plastic
					<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)					
Name Christina M. Swick, Lewis & Harrison, 122 C Street NW Suite 740, Washington DC 20001		Title Agent for Ionics, Inc.		Telephone No. (Include Area Code) 202-393-3903 x16	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				6. Date Application Received (Stamped)	
2. Signature <i>Christina M. Swick</i>		3. Title Agent for Ionics, Inc.			
4. Typed Name Christina M. Swick, Lewis & Harrison		5. Date April 21, 2005			



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

296986

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. (In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
<input checked="" type="checkbox"/> Certification must be submitted	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

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Name		Title		Telephone No. (Include Area Code)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.					6. Date Application Received (Stamped)
2. Signature		3. Title			
4. Typed Name		5. Date			

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2. Confidential Statement of Formula (EPA Form 8570-4);
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4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

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SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-job," reregistrations, etc.

1-5. Self-explanatory.

6. EPA Use Only.....

Receipt for Section 3

S: 771950

Regulatory Type: Product Information - Section 3

Regulation: ☒ Yes ☐ No

Application Type: Amendment

Fast Track Review: ☒ Yes ☐ No

Company: 35001 JONES, INCORPORATED

Risk Manager: Amphioxus Division, Risk Management Team

Product #: 35001-2 Product Name: RYANINE

Overlord:

Ms To: Section: Product Name:

Application Date: 21-Apr-2005

ic

APR 22 2005

22-Apr-2005

ic

Print End Date: 22-Apr-2005

ic

Risk Manager: Date: 28-Apr-2005

ic

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

MINOR FORMULATION AMENDMENT TO ADD ADDITIONAL
SOURCES OF INERT INGREDIENT

New Ingredient
Effective Date:


New Ingredient
Effective Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Figure 1

STRENGTH
Color: Black (1) - 100000



NAME	
ADDRESS	
CITY	
STATE	
ZIP	
PHONE	
DATE	
NAME	

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 28, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CHRISTINA M. SWICK
LEWIS & HARRISON, AGENT FOR
IONICS, INCORPORATED
122 C STREET N.W., SUITE 740
WASHINGTON, D.C. 20001

PRODUCT NAME: HYGENE
COMPANY NAME: IONICS, INCORPORATED
OPP IDENTIFICATION NUMBER: 296986
EPA FILE SYMBOL: 35900-2
EPA RECEIPT DATE: 04/22/05

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 33, at (703) 308-6341.

Sincerely,

A handwritten signature in cursive script, appearing to read "Julie".

Front End Processing Staff
Information Services Branch
Information Resources and Services Division

Receipt for Section 3

Regulatory Type: ☐ New Drug Application - Section 3 ☒ New Drug Application - Section 3
Application Type: ☐ New Drug Application ☒ New Drug Application
Company: ☐ New Drug Application ☒ New Drug Application

File Label
New Drug Application

Risk Manager: ☐ New Drug Application ☒ New Drug Application
Product ID: ☐ New Drug Application ☒ New Drug Application
Product Name: ☐ New Drug Application ☒ New Drug Application
Overview: ☐ New Drug Application ☒ New Drug Application
Me Top: ☐ New Drug Application ☒ New Drug Application
Section: ☐ New Drug Application ☒ New Drug Application

Application Date: 21-Apr-2005 ☒ New Drug Application 22-Apr-2005 ☒ New Drug Application
First End Date: 22-Apr-2005 ☒ New Drug Application ☒ New Drug Application

Fast Track: ☐ New Drug Application ☒ New Drug Application

Receipt Description:

MINOR FORMULATION AMENDMENT TO ADD ADDITIONAL
SOURCES OF INERT INGREDIENT

Form A: ☐ Signature Date: ☐ New Drug Application

Form B: ☐ Signature Date: ☐ New Drug Application

✓

Receipt for Section 3

777500			
Regulatory Type	Product Registration - Section 3	Registration	<input checked="" type="radio"/> Yes <input type="radio"/> No
Application Type	Amendment	Priority Review	<input checked="" type="radio"/> Yes <input type="radio"/> No
Company	BMS Corporation		
Risk Manager	Administrative Division, Regulatory Affairs		
Product #	AS001-2	Product Name	TYGAL
Overseer			
File Top			
Section			
Application Date	21-Apr-2005	Review Date	22-Apr-2005
Front End Date	22-Apr-2005	Back End Date	
Fast Track	<input type="checkbox"/>	Priority Review	<input type="checkbox"/>
Reason Description	MINOR FORMULATION AMENDMENT TO ADD ADDITIONAL SOURCES OF INERT INGREDIENT		
Form A	<input type="checkbox"/>	Signature Date	
Form B	<input type="checkbox"/>	Signature Date	

Fee for Service

This package includes the following

☐ New Registration

☒ Amendment

☐ Waiver Request and type

☐ 100% ☐ 50% ☐ IR-4 ☐ Minor ☐ Fed/state

for Division

☐ RD

☒ AD

☐ BPPD

Risk Mgr.

33

Receipt Nos. S-

777859

EPA File Symbol/Reg. No.

35900-2

Pin-Punch Date:

4-22-05

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount due: \$

Parent/Child Decisions:

☐ Voluntary Payment Request

% Reduction

Reviewer: K. Leary / J. Fish

Date: 4/25/05

Remarks: (use back if needed)

DECISION PKG. NO. 356602SUBM. DUE DATE July 21, 2005SUBMISSION BAR CODE # 777859REVIEWER P. JenkinsCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 359002 PM 33 ACTION CODE 345

DESCRIPTOR _____ FQPA _____ NFQPA _____

☐ CHILD RESISTANT PACKAGING: ☐ REQUIRED ☐ NOT REQUIREDREGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

04/21/0504/22/0504/28/05

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL ☐ SELECTIVE
☐ NOT SUBMITTED ☐ N/A☐ SUBMITTED ☐ NOT SUBMITTED
☐ N/A

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY _____ [] [] [] []

EFFICACY _____ [] [] [] []

ACUTE TOX. _____ [] [] [] []

RASSB TOX. _____ [] [] [] []

ENVIRON. FATE _____ [] [] [] []

FISH/WILDLIFE _____ [] [] [] []

OTHER: _____ [] [] [] []

STATUS _____

RESPONSE CODE _____

RESPONSE DATE _____

DATA PACKAGE BEAN SHEET

Date: 02-May-2005

Page 1 of 1

***** Registration Information *****

Registration: 35900-2 - HYGENE

Company: 35900 - IONICS, INCORPORATED

Risk Manager: RM 33 - Marshall Swindell - (703) 308-6341 Room# CM-2 308H

Risk Manager Reviewer: Portia Jenkins PJENKINS

Sent Date: _____

Calculated Due Date: 21-Jul-2005

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (345) FORMULA CHANGE; TECHNICAL;

Ingredients: 072501, Silver(1.05%)

***** Data Package Information *****Expedite: ☐ Yes ☒ No

Date Sent: 02-May-2005

Due Back: _____

DP Ingredient: 072501, Silver

DP Title: _____

CSF Included: ☐ Yes ☒ NoLabel Included: ☐ Yes ☒ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: AD / PSB

5/24/05

Administrative Due Date: 16-Jun-2005

Team Name: CTT

5/24/05

Negotiated Due Date: 6/21/05

Reviewer Name: Bob T

5/26/05

Projected Completion Date: 6/7/05

Contractor Name: _____

***** Studies Sent for Review *****

No Studies

***** Additional Data Package for this Decision *****

No Additional Data Packages

***** Data Package Instructions *****

Product Chemistry Review

Action Code 345

S. No. 777865, D. No. 356602

Adm Due Date 07-21-05, Sci Due Date 06-21-05

Please review and determine if the information submitted is acceptable of add source of inert ingredient.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

June 8, 2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Hygene

DP Barcode: D316506

Manufacturing-use [] OR

Reg. No. Or File Symbol: 35900-2

End-use Product [X]

TO: Marshall Swindell PM 33 / Portia Jenkins, Team Reviewer
Regulatory Management Branch I
Antimicrobials Division (7510C)

FROM: Robert Turpin, Chemist *R.T.*
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

K.P. Hicks
6/8/05

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Product Formulation

Active Ingredient(s)

% by wt.

Silver 1.05

BACKGROUND: The registrant has submitted an amendment to add alternate sources of the inert ingredient to the Confidential Statement of Formula (CSF) of the subject product. In support of the amendment, the registrant has submitted technical data and Material Safety Data Sheets of each of the alternate products.

FINDINGS:

The alternate sources of the inert ingredient, activated carbon, are acceptable.

RECOMMENDATIONS: None.

31910-2

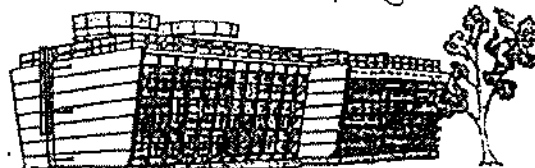
9/28/2000

Page 1 of 6



a division of National Starch and Chemical Company

909 Mueller Drive
PO Box 5401
Chattanooga, TN 37406
Phone: 423-629-1405
Fax 423-698-8723

**AQUATREAT®**

Polymers and Microbiocides for
Industrial Water Treating

Technical Information

TB 5066
7/21/00

ACCEPTED

SEP 28 2000

Under the Federal Insecticide, Fungicide, and
Rodenticide Act as amended, for the
pesticide, registered under
EPA Reg. No. 31910-2

AQUATREAT® DNM-30

EPA REG. NO. 31910-2

ADDITIONAL USE PATTERN #1:

SEAWATER COOLING TREATMENT
(for marine use only)

AQUATREAT® DNM-30 is a highly effective antifoulant and seawater biocide designed to control the growth of microorganisms (bacteria and fungi) and barnacle larvae on shipboard seawater heat exchangers.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product must not be used on any food or field crop or to formulate any product for use on any food or field crop.

To achieve best control of Fouling, AQUATREAT DNM-30 or seawater cooling treatment should be applied to a clean system. If fouling is present, it is recommended that the system be thoroughly cleaned prior to its use.

For best results, treat the system with 10 ppm of AQUATREAT DNM-30 for 100 minutes every 3-4 days. To treat at 10 ppm, feed at the rate of 3.88 pounds per 100 tons/hr. (50.72 fl. oz. or 1.5 liters per 100 tons/hr.) of system flow rate. The frequency of dosing may be less, depending on the degree of fouling.

AQUATREAT DNM-30 is completely soluble in seawater and can be conveniently fed directly from the drum or from a dosing tank. The best point of feed is as early as possible in the system, preferably before any strainer or heat transfer surfaces. The most common point is to dose the sea chest.

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PAGE 2
ADDITIONAL USE PATTERN #1
AQUATREAT DNM-30
EPA REG. NO. 31910-2

AQUATREAT DNM-30 should not be fed to a system while the seawater is being drawn as make-up for an evaporator or water maker. Either isolate the evaporator or shut it down while AQUATREAT DNM-30 is being dosed and for at least 30 minutes afterwards.

TYPICAL PROPERTIES

ACTIVE INGREDIENTS:

Sodium Dimethyldithiocarbamate

15%

Nabam (Disodium ethylene bis-dithiocarbamate)

15%

INERT INGREDIENTS

70%

TOTAL

100%

ACCEPTED

SEP 28 2000

Under the Federal Insecticide, Fungicide, and
Rodenticide Act as amended, for the
pesticide, registered under
EPA Reg. No. 31910-2

APPEARANCE

AQUATREAT DNM-30 is a clear, yellow-green liquid with a density of 1.175 grams/cc at 20°C (9.8 lbs./gal.) and has a characteristic sulfur odor.

pH is 10.5-12.4, and the product is completely soluble in all proportions in both fresh and seawater.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING: Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. All industrial workers applying this product must wear coveralls over a long-sleeved shirt and long pants, shoes, socks, and chemical-resistant gloves. During dilution, a chemical-resistant apron and goggles or face shield must also be worn. Harmful if swallowed. Avoid contamination of food and feedstuffs.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish. Do not apply (or use) in estuarine oil fields where drilling fluids (muds) are discharged in the surface water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

1. **PROHIBITIONS:** Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.
2. **PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.
3. **CONTAINER DISPOSAL:**
 - (a) Reseal container and offer for reconditioning, or
 - (b) Metal Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other approved state and local procedures.

Plastic Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed, by state and local authorities, by burning. If burned, stay out of smoke.
4. **GENERAL:** Consult federal, state, or local disposal authorities for approved alternative procedures.

FIRST AID
IF IN EYES

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING

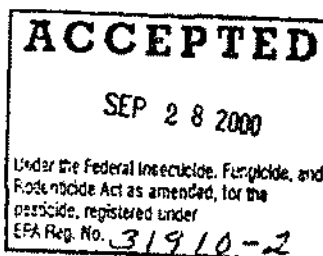
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

IF INHALED

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
- Call a poison control center or doctor for further treatment advice.



PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING

Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. All industrial workers applying this product must wear coveralls over a long-sleeved shirt and long pants, shoes, socks, and chemical-resistant gloves. During dilution, a chemical-resistant apron and goggles or face shield must also be worn. Harmful if swallowed. Avoid contamination of food and feedstuffs.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not apply (or use) in estuarine oil fields where drilling fluids (muds) are discharged in the surface water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

AQUATREAT DNM-30 is a highly effective bactericide and fungicide for use in controlling the growth of bacteria and fungi found in paper mills, drilling fluids, secondary and tertiary petroleum recovery, fracturing fluids, workover and completion fluids, flue gas desulfurization thickeners, hydrocarbon fluids storage, beet sugar mills, and cane sugar mills.

AQUATREAT DNM-30, in addition to being a bactericide and fungicide, is a highly effective algacide for use in controlling the growth of algae, as well as bacteria and fungi found in industrial recirculating water cooling towers, evaporative condensers, and air washers.

STORAGE AND DISPOSAL

1. PROHIBITIONS

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

2. PESTICIDE DISPOSAL

Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

3. CONTAINER DISPOSAL

- Reseal container and offer for reconditioning, or
- Metal Containers:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other approved state and local procedures.

Plastic Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

4. GENERAL

Consult federal, state or local disposal authorities for approved alternative procedures.

AQUATREAT® DNM-30

ACTIVE INGREDIENTS

Gadidum Dimethyldithiocarbamate 15%

Nabam (Disodium Ethylene

Bis-dithiocarbamate) 15%

INERT INGREDIENTS 70%

TOTAL 100%

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID

IF IN EYES	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF INHALED	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also call 1-888-456-4218 day or night for emergency medical treatment information.

See Side Panel For
Additional Precautionary Statements.

ACCEPTED

SEP 28 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 21910-2

AAALCO

Manufactured by:

ALCO CHEMICAL DIVISION

National Starch and Chemical Company
909 Mueller Dr. • P.O. Box 5401 • Chattanooga, TN 37406
423-629-1405
FAX 423-698-8723

E.P.A. Establishment No. 31810-TN-1

E.P.A. Registration No. 31910-2

Net Contents: Liquid

See Markings on Top of Drum for Net Weight

Cooling Towers and Air Washers



DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

This product must not be used on any food or field crop or to formulate any product for use on any food or field crop.

See Technical Data Sheet(s) for additional use pattern(s).

INDUSTRIAL RECIRCULATING WATER COOLING TOWER AND EVAPORATIVE CONDENSERS

Dosage for industrial recirculating water cooling tower or evaporative condensers will depend on the condition of the system prior to treatment initiation. Systems which are heavily contaminated should be cleaned first. Apply AQUATREAT DNM-30 to the cleaned system or when growth is first noticed, according to the following schedule: INITIAL DOSE: Apply 13.06-43.60 ounces of product per each 1000 gallons of water in the system (120-400 ppm). This dose may be repeated once, twice or three times weekly or as required to control the growth of slime-forming organisms.

SUBSEQUENT DOSE: When microbial control is evident add 2.18-4.36 fluid ounces of AQUATREAT DNM-30 per 1000 gallons of water (20-40 ppm) in the system every three days or as needed.

AIR WASHERS

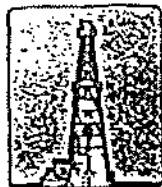
In treating air washer systems pre-clean by introducing a suitable detergent solution into the system and allow air washers to run with fan off for two hours. Check all nozzles and manually clean those that are plugged.

Feeding: AQUATREAT DNM-30 may be fed directly from the drum or diluted with water and fed by any suitable feed system. AQUATREAT DNM-30 should be dosed directly into the sump or basin or any other location where good distribution can be assured.

INITIAL DOSE: Apply 13.06-21.60 ounces of product per each 1000 gallons of water in the system (120-200 ppm). This dose may be repeated once, twice or three times weekly or as required to control the growth of slime-forming organisms.

SUBSEQUENT DOSE: When microbial control is evident add 2.18-4.36 fluid ounces of AQUATREAT DNM-30 per 1000 gallons of water (20-40 ppm) in the system every three days or as needed.

Drilling Fluids



DRILLING FLUIDS

AQUATREAT DNM-30 is a highly effective micro-biocide for use in controlling growth of fungi and bacteria found in water based drilling muds. It is especially useful in muds containing starches, Xanthanate gums, and wood sugars. The uncontrolled growth of these fungi and bacteria can cause increased corrosion, undesirable odors, and degradation of the drilling mud, especially fluid loss properties.

AQUATREAT DNM-30 is used at the rate of 1 to 5 gallons per 100 bbl. of mud. (0.02% to 0.1%). It can be used directly from the shipping container or pre-diluted with water. It can be put in through the mud hopper or added to the pump suction.

SECONDARY AND TERTIARY PETROLEUM RECOVERY

AQUATREAT DNM-30 is a highly effective micro-biocide for use in controlling the growth of fungi and bacteria found in secondary and tertiary petroleum recovery waterflood systems.

AQUATREAT DNM-30 can be injected directly from the shipping container. It should be thoroughly mixed into the produced water, fresh or salt water or commingled water or the secondary or tertiary oil recovery waterflood systems for effective micro-organism control. It may also be diluted with water for injection.

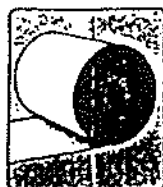
AQUATREAT DNM-30 is used at the rate of 1 pint per 100 bbl. of water for growth inhibition of *Bacillus Cereus* and *Desulfovibrio desulfuricans* and 1.1 to 1.8 gallons per 100 bbl. of water for heterotrophic bacteria including *Pseudomonas*. It is also effective against many fungi such as *Aspergillus*, *Penicillium* and *Trichoderma* at the 1 pint per 100 bbl. of water.

FRACTURING FLUIDS

AQUATREAT DNM-30 is a highly effective micro-biocide for controlling the growth of bacteria in fracturing fluids. The application rates are 0.81 to 4.3 lbs. per 1000 gallons of fracturing fluids. AQUATREAT DNM-30 may be added and premixed prior to the fracturing operation or may be added directly from the drum to the blender during the operation.

WORKOVER & COMPLETION FLUIDS

AQUATREAT DNM-30 is a highly effective micro-biocide for use in controlling the growth of fungi and bacteria found in water based workover and completion fluids. AQUATREAT DNM-30 is used at the rate of 1-4 quarts per 1000 gallons (0.025%-0.100%) of workover or completion fluids.



FLUE GAS DESULFURIZATION (FGD) THICKENERS

(NOT APPLICABLE IN CALIFORNIA)

AQUATREAT DNM-30 is effective in controlling anaerobic bacteria (SRB's) in flue gas desulfurization (FGD) thickeners.

AQUATREAT DNM-30 is metered directly to the thickener center well. It is fed at the rate of 50 to 500 ppm of product on a frequency of at least once per week or as required.

HYDROCARBON FLUIDS

AQUATREAT DNM-30 is a highly effective fungicide and bactericide for use in fuel oil (No. 2 oil, intermediate fuel oil and No. 6 oil), lubricating oil and hydraulic fluids in marine environments.

AQUATREAT DNM-30 is applied initially at a level of 2.3 pints per 1000 gallons of contaminated liquid (300 ppm by weight). Subsequent dosages may be decreased once the contaminants have been brought under control.

PAPER MILLS

Dosage will vary from 0.1 to 2.0 pounds (0.04 to 0.81 quarts) of AQUATREAT DNM-30 per ton of finished paper depending on the type of stock, complexity of the system, quality of raw water, and type and degree of contamination.

FEEDING: AQUATREAT DNM-30 may be drip fed continuously from the drum or fed by suitable chemical pumps such as adjustable proportioning types; variable speed, positive displacement types; or by the reciprocating type. This product should be fed as early as possible in the system at such points including the hydropulper, machine chest or broke system.

AQUATREAT DNM-30 can be used to control slime on machines which can make paper and paperboard for use in food packaging.

BET SUGAR MILLS

AQUATREAT DNM-30 should be fed directly into the pulp press water during sugar extraction of beets to keep equipment free of bacterial slime deposits. It is to be used at the rate of 10-20 ppm of raw beets sliced, and fed continuously with a metering pump. A portion of the AQUATREAT DNM-30 may be fed into other streams entering the diffuser each at a minimum rate of 4 ppm. The maximum total rate of all streams to be fed is 20 ppm. Refer to Composite Table 1 for the proper dosage in milliliters and ounces of AQUATREAT DNM-30 to be used per minute.

CANE SUGAR MILLS

AQUATREAT DNM-30 is a liquid which should be fed directly into the cane juice so that the treated juice circulates to all parts of the mill tandem. The point or points of addition will depend on mill design. Frequently the dosage will be split between

the crusher juice and juice from the last mill. The best addition point is to the juice which is circulated back to the crusher from the first mill. Do not add this product to the maceration water.

AQUATREAT DNM-30 should be fed continuously at the rate of 10-20 parts of product per million parts of cane ground per day. 10 ppm of product is the standard dosage. This may be raised up to a maximum of 20 ppm, if necessary. Conditions warranting some increase would be warranted when grinding cane damaged through freezing, poor weather or delays between cutting and grinding. See feeding directions which follow.

Proper feed of AQUATREAT DNM-30 is best obtained through the use of a chemical feed pump such as the adjustable proportioning type; the variable speed, positive displacement type; or the reciprocating type. The required dosage will depend on the average daily rate of cane ground. Refer to composite table 1 for the proper dosage in milliliters and ounces of AQUATREAT DNM-30 to be used per minute.

Do not exceed feed rate of 4 gallons (39.2 pounds) of product per 1000 short tons of cane ground per twenty-four hours.

The use of AQUATREAT DNM-30 does not replace good housekeeping. This should include regular cleaning at least once per shift. Regular hosing with hot water and steam of mills, bagacillo conveyors, and screens is essential for maintaining efficient control of microbiological slime and sucrose losses.

COMPOSITE TABLE 1

SHORT TONS OF CANE GROUND OR RAW BEETS SLICED PER DAY	Rate of Feed of AQUATREAT DNM-30			
	10 ppm		20 ppm	
	ml/mfn	oz/mfn	ml/min	oz/mfn
1,000	5.5	0.186	11	0.372
2,000	11.0	0.372	22	0.744
3,000	16.5	0.558	33	1.115
4,000	22.0	0.744	44	1.487
5,000	27.5	0.930	55	1.859
6,000	33.0	1.115	66	2.231
7,000	38.5	1.301	77	2.603
8,000	44.0	1.487	88	2.974
9,000	49.5	1.673	99	3.347
10,000	55.0	1.859	110	3.718

For Chemical Emergency
Spill, Leak, Fire, Explosive, or Accident
Call CHEMTREC — Day or Night
1-800-424-9300

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material, when such use and/or handling is contrary to label instructions.

ATTACHMENT 1

2025

DECISION PKG. NO. 338472SUBM. DUE DATE 5-02-04SUBMISSION BAR CODE # 753455REVIEWER P. JenkinsCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 35900-2 PM 33 ACTION CODE 302

DESCRIPTOR _____ FQPA _____ NFQPA _____

☐ CHILD RESISTANT PACKAGING: ☐ REQUIRED ☐ NOT REQUIRED
REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

01/28/0402/02/0402/04/04

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL ☐ SELECTIVE ☐ SUBMITTED ☐ NOT SUBMITTED
☐ NOT SUBMITTED ☐ N/A ☐ N/A

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY _____

EFFICACY _____

ACUTE TOX. _____

RASSE TOX. _____

ENVIRON. PATE _____

FISH/WILDLIFE _____

OTHER: _____

STATUS _____

RESPONSE CODE

17

RESPONSE DATE

MAR 18 2004 ✓

SCIENCE GROUP	DIVISION	BRANCH	SECTION	CSF Y/N	LABEL Y/N
CHEMISTRY	AD	EASSE	CTT		
EFFICACY	AD	EASSE	EET		
ACUTE TOX	AD	EASSE	CTT		
RISK TOX	AD	RASSE	TEAM 1		
EXPOSURE	AD	RASSE	TEAM 1		
ENV. FATE	AD	RASSE	TEAM 2		
FISH/WILD	AD	RASSE	TEAM 2		

INSTRUCTIONS
INCLUDE MRID#S

INSTRUCTIONS

INSTRUCTIONS

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 18 2004

Lewis & Harrison, Agent for
Ionics, Inc.
c/o 122 C Street, N.W. Suite 720
Washington, DC 20001

Attention: Christina M. Swick

Subject: **HYgene**
EPA Registration No. 35900-2
Amendment Application Dated: January 28, 2004
EPA Received Date: February 2, 2004

This will acknowledge receipt of your letter dated January 28, 2004, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, in response to PR-Notice 2001-1 "First Aid Statement". This information is acceptable and will be placed in subject product file.

If you have any comments or questions concerning this letter, please contact me at 703-308-6341 or Portia Jenkins at 703-308- 6230

Sincerely,



Marshall Swindell
Product Manager (33)
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Receipt for Section 3

S: 753455

Print Letter

Enter More Information

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Company: 35900 CHICS, INCORPORATED

V

Risk Manager: Antimicrobials Division, Risk Management Team 33

Product #: 35900-2 Product Name: HYGENE

Override:

Me Too

Me Too

Section3:

Product Name:

Application Date: 02-Jan-2004

OPP Rec'd Date: 02-Feb-2004

Front End Date: 06-Feb-2004

Risk Manager Send Date: 06-Feb-2004

Fast Track: ☐ Studies: ☐ New Ingredient: ☐

Receipt Description:

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A:

Signature Date:

Form B:

Signature Date:

Claimed confidential by submitter

FQPA

SUBMISSION BAR CODE # 5613902 REVIEWER KLeary-Munk

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 35900-2 PM 33 ACTION CODE 362

DESCRIPTOR Formula Amendment

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
[] NON-RESIDENTIAL USE ONLY
[] NOT APPLICABLE

REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

04 03 02

04 03 02

04 05 02

~~METHOD OF SUPPORT~~

~~FORMULATORS EXEMPTION~~

[] CITE ALL
[] SELECTIVE
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

[] SUBMITTED
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #

DATE
SENT

DUE
DATE

DATE -
RETURNEE

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE 17

RESPONSE DATE

MAY 21 2002



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 21 2002

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Christina M. Swick,
Agent for Ionics, Inc.
Ionics, Inc.
3039 Washington Pike
Bridgeville, PA 15017

Subject: HYgene Bacteriostatic Water Filter Media
EPA Registration Number 35900-2
Your Submission Dated April 3rd, 2002
EPA Received Date April 3rd, 2002

Dear Ms. Swick:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add the alternate suppliers for the inert ingredient, activated carbon, for the basic formulation, and add an additional supplier of the active ingredient, is acceptable:

- Basic formula
- Data Matrix

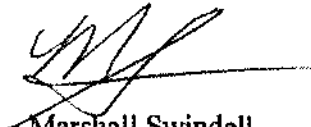
Acceptable Data

The basic Confidential Statement(s) of Formula dated April 1st, 2002, is acceptable.

General Comments

Should you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,


Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

**EPA**

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number
287810

Application for Pesticide - Section I

1. Company/Product Number 35900-2	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HYgene Bacteriostatic Water Filter Media	PM# Team 33	
5. Name and Address of Applicant (Include ZIP Code) Ionics, Inc. 3039 Washington Pike Bridgeville, PA 15017 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Formula Amendment - Revised Basic Formula**Section - III**

1. Material This Product Will Be Packaged in:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Christina M. Swick, Lewis & Harrison, 122 C Street NW Suite 740, Washington DC 20001	Title Agent for Ionics, Inc.	Telephone No. (Include Area Code) 202-393-3903 x16
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature Christina M. Swick	3. Title Agent for Ionics, Inc.	
4. Typed Name Christina M. Swick, Lewis & Harrison	5. Date April 3, 2002	



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

287810

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code) <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner In Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		Date Application Received (Stamped)
2. Signature	3. Title	
4. Typed Name	5. Date	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). If not exempted by 40 CFR 152.61 (b) (4));
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled use.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Label of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-top," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.

Claimed confidential by submitter



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address and Telephone Number Ionics Inc.: 3039 Washington Pike, Bridgeville, PA 15017 / 202-393-3903 (Agent)	EPA Registration Number/ File Symbol 35900-2
Active Ingredient(s) and/or representative test compound(s): Silver (EPA A.I.# 72501)	Date April 3, 2002
General use pattern(s) (list all those claimed for this product using 40 CFR Part 158) Aquatic Food Crop	Product Name HYgene Bacteriostatic Water Filter Media

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

- | | |
|--|---|
| <input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | <input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). |
|--|---|

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Christina M. Swick</i>	Date April 3, 2002	Typed or Printed Name and Title Christina M. Swick - Agent for Ionics Inc.
--	------------------------------	--



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

04/05/2002

CHRISTINA M. SWICK, AGENT FOR
IONICS, INCORPORATED
122 C STREET, NW, SUITE 740
WASHINGTON DC 20001

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: HYGENE BACTERIOSTATIC WATER FILTER MEDIA
COMPANY NAME: LEWIS & HARRISON FOR IONICS
OPP IDENTIFICATION NUMBER: 287810
EPA REGISTRATION NUMBER: 35900-2
EPA RECEIPT DATE: 04/03/2002

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Marshall Swindell, Product Manager 33, at (703)-308-6230.

Sincerely,

J. Swick

Front End Processing Staff
Information Services Branch
Program Management and Support Division



IONICS

IONICS, INCORPORATED
BRIDGEVILLE PLANT

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE
BACTERIOSTATIC WATER FILTER MEDIA
EPA REGISTRATION NO. 35900-2

HYGENE BACTERIOSTATIC WATER FILTER MEDIA

- Removes objectionable tastes, odors, and color from municipally treated tap water
- Inhibits the growth of bacteria within the media bed to prolong the life of the filter

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 13 1995

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under EPA Reg. No.

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

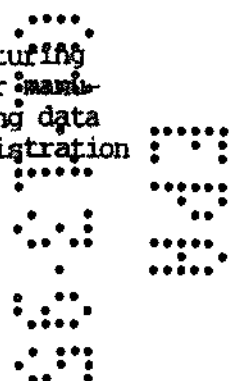
Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in HYgene Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a buildup or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.



HYGENE BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Hygene Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 Lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 0.5 gpm per 0.25 lb. of media. Bed depth must be at least twice the diameter.

Use on cold water only.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

SPECIFICATIONS

ACTIVE INGREDIENT

Metallic Silver - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container with excludes moisture and chemical fumes.

MESH SIZE

12 X 30 U.S. Sieve Series
Or
20 X 50 U.S. Sieve Series

PACKAGING

6 Cu. Ft. Fiber Drums
1 Cu. Ft. Carton

WEIGHT

30-34 Lbs. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 13 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide
Act, this product is
registered under EPA Reg. No.

35900-2



BACTERIOSTATIC WATER FILTER MEDIA

Inhibits the growth of bacteria

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and chemical fumes.

EPA Reg. No. 35900-2

EPA Est. No. 35900 PA 01

ACTIVE INGREDIENT

METALLIC SILVER1.05%

INERT INGREDIENT

ACTIVATED CARBON98.95%

DIRECTIONS FOR USE:

LOT NO. _____

NET CONTENTS _____

cu. ft.

Flow rate is not to exceed 15 GPM per cu. ft. of media. Bed depth must be at least twice the diameter.

DISPOSAL OF SPENT MEDIA: _____

Retain shipping carton and plastic liner for disposing of exhausted filter media with trash.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment

IONICS, INCORPORATED 3039 Washington Pike, Bridgeville, Penna. 15017



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0050

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DATA MATRIX

Date April 3, 2002		EPA Reg. No./File Symbol 35900-2		Page 1 of 1	
Applicant's/Registrant's Name & Address: Ionics, Inc. 3039 Washington Pike, Bridgeville, PA 15017		Product HYgcnc Bacteriostatic Water Filter Media			
Ingredient(s): Silver (A.I.# 72501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
61-1 to 62-3	Product Identity, Composition and Analysis				Waived ¹
63-2 to 63-9	Physical/Chemical Properties				Waived ¹
71-1(a)	Acute Avian Oral Toxicity - Quail/Duck	CITE-ALL	See Attachment	PAY	
71-2(a)	Avian Dietary Toxicity - Quail/Duck	CITE-ALL	See Attachment	PAY	
71-2(b)	Acute Avian Dietary - Duck				Waived ¹
72-1(a)	Freshwater Fish Toxicity - Bluegill				Waived ¹
72-1(c)	Fish Toxicity - Rainbow Trout	CITE-ALL	See Attachment	PAY	
72-2(a)	Freshwater Invertebrate Toxicity	CITE-ALL	See Attachment	PAY	
81-1	Acute Oral Toxicity				Waived ¹
81-2	Acute Dermal Toxicity				Waived ¹
81-3	Acute Inhalation Toxicity				Waived ¹
81-4	Primary Eye Irritation				Waived ¹
81-5	Primary Dermal Irritation				Waived ¹
81-6	Skin Sensitization				Waived ¹
161-1 to 165-5	Environmental Fate				Waived ¹

FOOTNOTE:

1. These data requirements were waived under the provisions of the Silver RED (June 1993).

Signature 	Name and Title: Christina M. Swick, Agent for Ionics, Inc.	Date April 3, 2002
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DATA MATRIX ATTACHMENT

Product Name: **HYgene Bacteriostatic Water Filter Media**
EPA Reg. No.: **35900-2**
Date of Data Matrix: **April 3, 2002**
Chemical: **Silver, A.I. Number 72501**

COMPANY# 008588 RGDEN FILTER COMPANY INC
* DATA TYPES * 4662 LANKERSHIN BLVD.
EU AT EC FW EF OT NORTH HOLLYWOOD CA
XX 91602

COMPANY# 010324 MASON CHEMICAL CO
* DATA TYPES * 721 W ALGONQUIN RD
EU AT EC FW EF OT ARLINGTON HEIGHTS IL
XX XX 60005

COMPANY# 014944 ATEK INDUSTRIES INC
* DATA TYPES * 5355 MCCONNELL AVE
EU AT EC FW EF OT LOS ANGELES CA
XX 90066

COMPANY# 018869 KING-HOLLER INT
* DATA TYPES * 606 WILSHIRE BLVD SUITE 501
EU AT EC FW EF OT SANTA MONI CA
XX XX 90401

COMPANY# 035968 CONSUMER ECOLOGY PROD., INC
* DATA TYPES * 101 S. W. FIFTH COURT
EU AT EC FW EF OT POMPANO BEACH FL
XX 33060

COMPANY# 037370 NATIONAL SAFETY ASSOCIATES, INC.
* DATA TYPES * 4260 EAST RAINES ROAD
EU AT EC FW EF OT MEMPHIS TN
XX XX 38118

COMPANY# 037664 TELEDYNE WATER PIK
* DATA TYPES * 1730 EAST PROSPECT ST
EU AT EC FW EF OT FORT COLLINS CO
XX XX XX 80521

COMPANY# 037756 WATER SAFE PRODUCTS, INC
* DATA TYPES * 8337 NIEMAN ROAD
EU AT EC FW EF OT LEXEXA KS
XX 66214

COMPANY# 038058 PUROLATOR CA. PUROLATOR, INC.
* DATA TYPES * 950 RANCHO CONEJO BLVD.
EU AT EC FW EF OT NEWBURY PARK CA
XX 91320

COMPANY# 038688 C. H. DEXTER DIVISION
* DATA TYPES * ONE ELM STREET
EU AT EC FW EF OT WINDSOR LOCKS CT
XX XX 06096

COMPANY# 039444 SUUNTO USA INC
AGENT FOR: KATADYN PRODUCTS, INC.
* DATA TYPES * 2151 LAS PALMAS DRIVE, SUITE F
EU AT EC FW EF OT CARLSBAD CA
XX XX 92009

DATA MATRIX ATTACHMENT

Product Name: **HYgene Bacteriostatic Water Filter Media**
EPA Reg. No.: **35900-2**
Date of Data Matrix: **April 3, 2002**
Chemical: **Silver, A.I. Number 72501**

COMPANY# 039938 NORTH AMERICAN SYSTEMS, INC.
* DATA TYPES * 24700 MILES ROAD
EU AT EC FW EF OT BEDFORD HTS. OH
XX XX 44146

COMPANY# 067712 ZODIAC POOL CARE, INC.
* DATA TYPES * 3420 NORTHWEST 53RD STREET
EU AT EC FW EF OT FT. LAUNDERDALE FL
XX XX 33309

COMPANY# 071227 AGION TECHNOLOGIES LLC
AGENT FOR: SINANEN COMPANY, LTD.
* DATA TYPES * 60 AUDUBON ROAD
EU AT EC FW EF OT WAKEFIELD MA
XX XX 01880

COMPANY# 071661 SRA INTERNATIONAL, INC.
AGENT FOR: INTELLIGENT BIOCIOES LLC
* DATA TYPES * 1850 M STREET, N.W., SUITE 290
EU AT EC FW EF OT WASHINGTON DC
XX XX XX 20036

COMPANY# 072977 HENRY JACOBY, REGULATORY CONSULTANT
AGENT FOR: ETI H2O, INC.
* DATA TYPES * 6709 ILEX COURT
EU AT EC FW EF OT NEW MARKET MD
XX XX 21774

COMPANY# 073148 SCIENTIFIC & REGULATORY CONSULTANTS
AGENT FOR: ISHIZUKA GLASS CO., LTD.
* DATA TYPES * 102 1/2 SOUTH CHAUNCEY STREET
EU AT EC FW EF OT COLUMBIA CITY IN
XX XX 46725

COMPANY# 073499 AMERICAN BIOTECH LABS
* DATA TYPES * 70 WEST CANYON CREST RD., SUITE 0
EU AT EC FW EF OT ALPINE UT
XX 84004

COMPANY# 073667 CHEMREG INTERNATIONAL, LLC
AGENT FOR: APYRON TECHNOLOGIES, INC.
* DATA TYPES * 2239-H TACKETS MILL ORIVE
EU AT EC FW EF OT LAKE RIDGE VA
XX 22192



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date April 3, 2002		EPA Reg. No./File Symbol 35900-2		Page 1 of 1	
Applicant's/Registrant's Name & Address: Ionics, Inc. 3039 Washington Pike, Bridgeville, PA 15017		Product HYgene Bacteriostatic Water Filter Media			
Ingredient(s): Silver (A.I.# 72501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Waived ¹
					Waived ¹
			See Attachment	PAY	
			See Attachment	PAY	
					Waived ¹
					Waived ¹
			See Attachment	PAY	
			See Attachment	PAY	
					Waived ¹
					Waived ¹
					Waived ¹
					Waived ¹
					Waived ¹
					Waived ¹
					Waived ¹

20 0 4

Signature 	Name and Title: Christina M. Swick, Agent for Ionics, Inc.	Date April 3, 2002
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DATA MATRIX ATTACHMENT

Product Name: **HYgene Bacteriostatic Water Filter Media**
EPA Reg. No.: **35900-2**
Date of Data Matrix: **April 3, 2002**
Chemical: **Silver, A.I. Number 72501**

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* DATA TYPES * 721 W ALGONQUIN RO
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COMPANY# 014944 ATEK INDUSTRIES INC
* DATA TYPES * 5355 MCCONNELL AVE
EU AT EC FW EF OT LOS ANGELES CA
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* DATA TYPES * 1730 EAST PROSPECT ST
EU AT EC FW EF OT FORT COLLINS CO
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COMPANY# 037756 WATER SAFE PRODUCTS, INC
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EU AT EC FW EF OT LEXEXA KS
XX 66214

COMPANY# 038058 PUROLATOR CA. PUROLATOR, INC.
* DATA TYPES * 950 RANCHO CONEJO BLVD.
EU AT EC FW EF OT NEWBURY PARK CA
XX 91320

COMPANY# 038688 C. H. DEXTER DIVISION
* DATA TYPES * ONE ELM STREET
EU AT EC FW EF OT WINDSOR LOCKS CT
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COMPANY# 039444 SUUNTD USA INC
AGENT FOR: KATADYN PRODUCTS, INC.
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* DATA TYPES * 60 AUDUBON ROAD
EU AT EC FW EF OT WAKEFIELD MA
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COMPANY# 071661 SRA INTERNATIONAL, INC.
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COMPANY# 072977 HENRY JACOBY, REGULATORY CONSULTANT
AGENT FOR: ETI H2O, INC.
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COMPANY# 073499 AMERICAN BIOTECH LABS
* DATA TYPES * 70 WEST CANYON CREST RD., SUITE D
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COMPANY# 073667 CHEMREG INTERNATIONAL, LLC
AGENT FOR: APYRON TECHNOLOGIES, INC.
* DATA TYPES * 2239-H TACKETS MILL DRIVE
EU AT EC FW EF OT LAKE RIDGE VA
XX 22192

ATTACHMENT 1

4

4

4

4

ATTACHMENT 2

4

4

5

9

NON-FQPA

SUBMISSION BAR CODE # 55875-99REVIEWER M TerryCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 35900-2 PM 33 ACTION CODE 350DESCRIPTOR PR Notice 2000-3

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
 [] NON-RESIDENTIAL USE ONLY
 [] NOT APPLICABLE

REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

10	17	00
----	----	----

10	20	00
----	----	----

10	23	00
----	----	----

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[] CITE-ALL
 [] SELECTIVE
 [] NOT SUBMITTED
 [] NOT APPLICABLE
 [] INCORRECT/RESUB

[] SUBMITTED
 [] NOT SUBMITTED
 [] NOT APPLICABLE
 [] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER _____

STATUS _____

RESPONSE CODE 37RESPONSE DATE NOV 02 2000 ✓

**IONICS****IONICS, INCORPORATED**

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE 412-257-2029 FAX 412-257-1270

October 17, 2000

U.S. Environmental Protection Agency
Office of Pesticides Programs
Registration Division (7504C)
401 M St., S.W.
Washington, D.C. 20460

Attn: Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division (7505C)

Re: PR Notice 2000-3
Ionics Product Registration Numbers: 35900-2; 35900-3; 35900-6; 35900-7; 35900-9;
35900-13; 35900-16; 35900-18; 35900-19; 35900-20 and 35900-21

Dear Mr. Swindell:

Pursuant to the above referenced PR Notice 2000-3 regarding First Aid Statements on Pesticide Product Labels, I am sending this letter as a formal confirmation of my communications and discussions with your Ms. Karen Leavy-Munk.

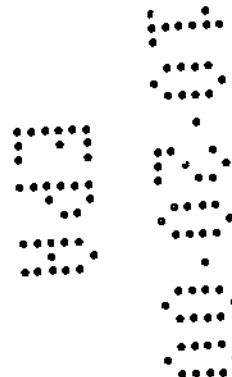
Basically, the above referenced products' labels only require the precautionary statement "Keep Out of Reach of Children" above the signal word "Caution", which already appears on all of our labeling. Additionally, we are to follow Toxicity Category IV across the board in regards to First Aid Statements due to the only active pesticide ingredient being Silver.

With this formal confirmation, shortly we will be forwarding our present labels with any modification required by Toxic Category IV, as outlined in the above referenced PR Notice, to your offices for review and acceptance.

Thank you for your continued support and guidance in our registration of product through the U.S. EPA.

Sincerely,
Ionics, Incorporated

John Henigin
Manager, Chemical Products and Projects



Reviewer ID

Submission No.

Data Package No.

5490661

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 35900-2 PM 31

Action Code 310

10 Descriptor (Amend/Resubmissions only)

Final printed labels

5 Intrastate Call-in ☐ (Y) Yes

☐ (N) No

15 Child-resistant Packaging

☐ (C) Certification

☐ (S) Service Person

20 Registration Type:

☐ (1) Conditional

☐ (2) Unconditional

☐ (R) Non-residential Use Only

☐ (N) Not-Applicable

25 Proposed Classification: 30 Final Classification:

☐ (R) Restricted

☐ (R) Restricted

☐ (G) General

☐ (N) Not Classified

35 Date on Application:

06 22 95
MO DAY YR

04 EPA Received Date:

06 22 95
MO DAY YR

40 Date Received by PM

06 22 95
MO DAY YR

80 Method of Support:

☐ (1) Cite-All

☐ (6) Owner Submission

☐ (4) Not Applicable

☐ (7) Total Submission

☐ (5) Not Submitted

☐ (8) Selective Method

Reviewers Requested:

CH

EF

PL

DEB

NDEB

TB

EEB

EFGB

DATE
SENT

DUE
DATE

DATE
RETURNED

RESPONSE
CODE

RESPONSE
DATE

115 FINAL Response ACTION Code 38

120 Respx 07/895

75-DAY RESPONSE DUE DATE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 18 1995

Ionics, Inc.
3039 Washington Pike
Brideville, PA 15017

Attention: Walter J. Polens

Subject: Hygene
EPA Registration Number 35900-2
Your Submission Dated June 22, 1995
EPA Received Date June 22, 1995

The submitted final printed labels have been placed in your product file. They have not been reviewed in accordance with the PR Notice 82-2.

If you have any questions concerning this letter, please contact Karen M. Leavy at (703)-305-6966.

Sincerely yours,



Marion J. Johnson
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

HYgene®

BACTERIOSTATIC WATER FILTER MEDIA

- This product is designed to remove objectionable tastes, odors, and color from municipally treated tap water.
- This product is designed to inhibit the growth of bacteria within the filter to prolong the life of the filter.

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA REGISTRATION NO. 35900-2

EPA ESTABLISHMENT NO. 35900 PA 01

ACTIVE INGREDIENT

Metallic Silver ----- 1.05%

LOT No. _____

INERT INGREDIENT

Activated Carbon ---98.95%

NET CONTENTS _____ cu. ft.

STORAGE -----

Store in closed container which excludes moisture and chemical fumes.

DISPOSAL OF SPENT MEDIA-----

When contents are exhausted, wrap in newspaper and discard in the trash.

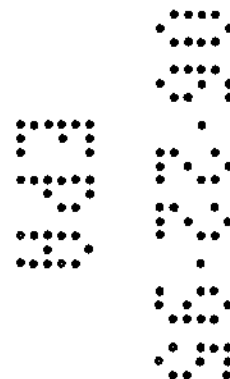
DIRECTIONS FOR USE-----

Refer to enclosed product data sheet.

IONICS, INCORPORATED, 3039 WASHINGTON PIKE, BRIDGEVILLE, PA 15017



IONICS
IONICS, INCORPORATED



**IONICS****IONICS, INCORPORATED**

BRIDGEVILLE PLANT

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

**HYGENE BACTERIOSTATIC
WATER FILTER MEDIA
EPA REGISTRATION NO. 35900-2
EPA ESTABLISHMENT NO. 35900 PA 01**

HYGENE BACTERIOSTATIC WATER FILTER MEDIA

- This product is designed to remove objectionable tastes, odors, and color from municipally treated tap water.
- This product is designed to inhibit the growth of bacteria in the filter to prolong the life of the filter

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual function of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in HYgene Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

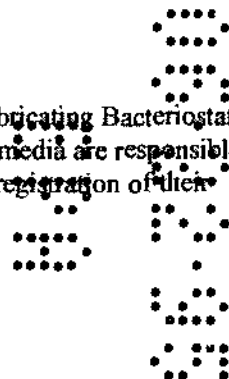
Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a buildup or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating Bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.

SEE REVERSE SIDE



HYGENE BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 Lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the in service flow rate is not to exceed 0.5 gpm per 0.25 Lb. of media. Bed depth must be at least twice the diameter.

USE WITH COLD WATER ONLY.

SPECIFICATIONS

ACTIVE INGREDIENT

Metallic Silver - 1.05%

INERT INGREDIENT

Activated Carbon - 98.5%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

20 X 50 U.S. Sieve Series

PACKAGING:

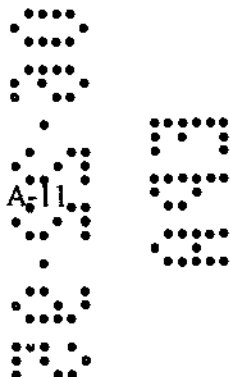
6 Cu. Ft. Fiber Drum
1 Cu. Ft. Carton.

WEIGHT

30-34 Lbs. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania



3/1/95

Reviewer ID

Submission No. 84809161

Data Package No. _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 33900-2 PM 31

Action Code 675

☒ [10] Descriptor (Amend/Resubmissions only) _____

☒ [5] Intrastate Call-in ☐ (Y) Yes ☐ (N) No

☐ [15] Child-resistant Packaging

☐ (C) Certification

☐ (S) Service Person

☐ (R) Non-residential Use Only

☐ (N) Not-Applicable

☒ [20] Registration Type:

☒ (1) Conditional ☐ (2) Unconditional

☐ [25] Proposed Classification: ☐ [30] Final Classification:

☐ (R) Restricted

☐ (R) Restricted

☐ (G) General

☐ (N) Not Classified

☐ [35] Date on Application:

☐ [04] EPA Received Date:

☐ [40] Date Received by PM

0 4 11 9 4
MO DAY YR

0 11 13 9 5
MO DAY YR

0 11 13 9 5
MO DAY YR

☐ [80] Method of Support:

☐ (1) Cite-All

☐ (6) Owner Submission

☐ (4) Not Applicable ☐ (7) Total Submission

☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

DATE
SENT

DUE
DATE

DATE
RETURNED

RESPONSE
CODE

RESPONSE
DATE

CH

EF

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DEB

NDEB

TB

EEB

EFGB

☐ [115] FINAL Response
ACTION Code 12

☐ [120] Response

031396

75-DAY RESPONSE DUE DATE: 7 / 11 / 95

<p style="text-align: center;">US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (75-767) WASHINGTON, DC 20460</p> <p>NOTICE OF PESTICIDE: <input type="checkbox"/> REGISTRATION <input checked="" type="checkbox"/> REREGISTRATION <i>(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</i></p>	<p>EPA REGISTRATION NO. 35900-2</p> <p>DATE OF ISSUANCE MAR 13 1995</p> <p>TERM OF ISSUANCE</p> <p>NAME OF PESTICIDE PRODUCT Hygiene</p>
<p>NAME AND ADDRESS OF REGISTRANT (Include ZIP code):</p> <p style="margin-left: 40px;">Ionics, Inc. 3039 Washington Pike Bridgeville, PA 15017</p>	
<p>NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.</p>	
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.</p> <p>A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.</p> <p>Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>Based on your response to the Silver Reregistration Eligibility Document, EPA has reregistered the above named product subject to the comments recorded in the succeeding paragraph. This action is taken under the authority of section 4(g)(2)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product. Make the following labeling changes before you release the product for shipment: Make the following labeling changes listed below before you release the product for shipment:</p> <ul style="list-style-type: none"> a. Add the phrase "EPA Registration No. 35900-2" b. Include the appropriate EPA Establishment No. c. Revise the statement "Removes....tap water" to read "This product is designed to remove objectionable tastes, odors, and color from municipally treated tap water." 	
<p><input type="checkbox"/> ATTACHMENT IS APPLICABLE</p>	
<p>SIGNATURE OF APPROVING OFFICIAL</p>	<p>DATE</p>

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

- d. Delete the phrase "General Classification" to read "Directions for Use."
- e. Revise the statement "Inhibits the growthfilter media" to read "This product is designed to remove objectionable tastes, odors, and color from municipally treated tap water."
- f. Place the statement "Keep Out of Reach of Children" directly above the signal word "Caution."
- g. Place the misuse statement "It is a violation of the Federal Law to use this product in a manner inconsistent with its labeling" directly under the subheading "Directions for Use."
- h. Delete the phrase "Filters suspended solids" from the product labeling.

The Confidential Statement of Formula dated April 11, 1994, is in compliance with PR Notice 91-2, it agrees with the label and is acceptable.

The label claim is in compliance with PR Notice 91-2 which is the nominal concentration and it agrees with the Confidential Statement of Formula and is acceptable.

A stamped copy of the labeling is enclosed for your records.

Submit one copy of final printed labeling before releasing the product in channels of trade with the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Sincerely,



Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)



IONICS

IONICS, INCORPORATED

BRIDGEVILLE PLANT

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

**HYGENE
BACTERIOSTATIC WATER FILTER MEDIA
EPA REGISTRATION NO. 35900-2**

HYGENE BACTERIOSTATIC WATER FILTER MEDIA

- Removes objectionable tastes, odors, and color from municipally treated tap water
- Inhibits the growth of bacteria within the media bed to prolong the life of the filter

ACCEPTED
with COMMENTS
in EPA Letter 11 ted:

MAR 13 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide
Act, this product is a pesticide
registered under EPA Reg. No.

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

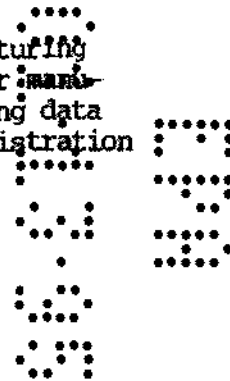
Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in HYgene Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a buildup or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.



HYGENE BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Hygene Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 Lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 0.5 gpm per 0.25 lb. of media. Bed depth must be at least twice the diameter.

Use on cold water only.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

SPECIFICATIONS

ACTIVE INGREDIENT

Metallic Silver - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container with excludes moisture and chemical fumes.

MESH SIZE

12 X 30 U.S. Sieve Series
Or
20 X 50 U.S. Sieve Series

PACKAGING

6 Cu. Ft. Fiber Drums
1 Cu. Ft. Carton

WEIGHT

30-34 Lbs. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAR 13 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
amended, this pesticide
registered under EPA Reg. No.

35900-2



BACTERIOSTATIC WATER FILTER MEDIA

Inhibits the growth of bacteria

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and chemical fumes.

EPA Reg. No. 35900-2

EPA Est. No. 35900 PA 01

ACTIVE INGREDIENT

METALLIC SILVER 1.05%

INERT INGREDIENT

ACTIVATED CARBON 98.95%

DIRECTIONS FOR USE:

LOT NO. _____

NET CONTENTS _____

cu. ft.

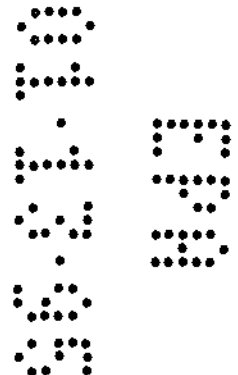
Flow rate is not to exceed 15 GPM per cu. ft. of media. Bed depth must be at least twice the diameter.

Retain shipping carton and plastic liner for disposing of exhausted filter media with trash.

DISPOSAL OF SPENT MEDIA:

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment

IONICS, INCORPORATED 3039 Washington Pike, Bridgeville, Penna. 15017



DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
A MANUFACTURING-USE ☒ OR AN END-USE PRODUCT ☐
DP Barcode 211524 Reg. No. or File Symbol No. 35900-2

TO: (PM Team Reviewer)
PM Team No. 31 *Walter Francis / Karen Leary*

FROM: (Chemist/Date) *Anna Skapers*
Product Chemistry Review Section
Registration Support Branch/RD (WH705W)

THRU: Harold Podall, Ph.D., Section Head
Registration Support Branch/RD (WH705W)

HP 2/7/95

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

*Confidential Statement of Formula dated 4-11-94
is in compliance with PR Notice 91-2, it agrees
with the label and is acceptable.*

*Label ingredient Statement is in compliance
with PR Notice 91-2 it is the nominal concentration,
it agrees with Confidential Statement of Formula
and is acceptable.*

Anna Skapers
2-7-95

PRODUCT CHEMISTRY REVIEW OF MP ☒ EP ☐
 DP BARCODE No.: 0211584 REG./File Symbol No.: 35900-2
 PRODUCT NAME: Hygiene Bacteriostatic Water Filter Media

1. Reviewer: Anna Skapen 2. Company: Ionics, Inc.
3. Type of Submission: Registration ☐ Reregistration ☒
 New ☐ Resubmission ☐ Amendment ☐ "ME-TOO" ☐
 Alternate Formulation ☐ Experimental Use Permit ☐
 Other (Specify) _____
4. If "Me-TOO" Registration, this product is ☐ is not ☐
 similar or substantially similar to EPA's Reg. No.: _____
- If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant.

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
- Non-integrated formulation system..... ☐
 - Are all technical grade active ingredients used registered?
 - yes ☐ • no ☐ , If no, specify _____
 - Integrated formulation system..... ☒
6. Clearance of intentionally added ingredients in the formulation for the intended use (indicate in the Confidential Appendix those that are not cleared; the PC Codes should be provided by the chemist on the CSF for those that are cleared):
- 6(a) Formulation intended for food use under 40CFR§180.1001:
- yes ☐ • no ☐ • Some are cleared, others are not ☐
 - Cleared under list: • c ☐ • d ☐ • e ☐
 - Are there any limitations for use as an inert under 40CFR§180.1001?
 - yes ☐ • no ☐ , If yes, specify N/A
- 6(b) Formulation intended for non-food use:
- yes ☒ • no ☐ • Some are cleared, others are not ☐
- 6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199. Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).

Anna.

DP BARCODE: D211584

CASE: 019229
SUBMISSION: S480969

DATA PACKAGE RECORD
BEAN SHEET

DATE: 02/02/95
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 675 RESUBMISSION
RANKING : 10 POINTS ()
CHEMICALS: 072501 Silver

01.0500%

ID#: 035900-00002 HYGENE
COMPANY: 035900 IONICS, INCORPORATED
PRODUCT MANAGER: 31 WALTER FRANCIS 703-305-6661 ROOM: CM2 248
PM TEAM REVIEWER: KAREN LEAVY 703-305-6966 ROOM: CM2 268
RECEIVED DATE: 01/13/95 DUE OUT DATE: 07/12/95

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 211584 EXPEDITE: N DATE SENT: 02/02/95 DATE RET.: / /
CHEMICAL: 072501 Silver

DP TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y

ASSIGNED TO	DATE	IN	DATE OUT	ADMIN DUE DATE: 05/03/95
DIV : RD	/	/	/	NEGOT DATE: /
BRAN: RSB	/	/	/	PROJ DATE: /
SECT: PCRS	/	/	/	
REVR : <i>Anna Skapars</i>	/	/	/	
CONTR: <i>2-7-95</i>	/	/	/	

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the revised Confidential Statement of Formula
and Product Labeling in response to the Silver RED.
Attn: Anna Skapars

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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DP BARCODE: D211584

CASE: 019229
SUBMISSION: S480969

DATA PACKAGE RECORD
BEAN SHEET

DATE: 02/02/95
Page 1 of 1

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SECT: PCRS	/	/	/	/	
REVR :	/	/	/	/	
CONTR:	/	/	/	/	

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Attn: Anna Skapars

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No evaluation is written for this data package

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DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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DP BARCODE: D211584

CASE: 019229
SUBMISSION: S480969

DATA PACKAGE RECORD
BEAN SHEET

DATE: 02/02/95
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

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RANKING : 10 POINTS ()
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CSF: Y LABEL: Y

ASSIGNED TO	DATE	IN	DATE	OUT	ADMIN DUE DATE: 05/03/95
DIV : RD	/	/	/	/	NEGOT DATE: / /
BRAN: RSB	/	/	/	/	PROJ DATE: / /
SECT: PCRS	/	/	/	/	
REVR :	/	/	/	/	
CONTR:	/	/	/	/	

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the revised Confidential Statement of Formula
and Product Labeling in response to the Silver RED.
Attn: Anna Skapars

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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United States Environmental Protection Agency
Washington, DC 20460

**CERTIFICATION WITH RESPECT TO
DATA COMPENSATION REQUIREMENTS**

Form Approved

OMB No. 2070-0106

Approval Expires 12-31-92

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	IONICS, INCORPORATED 3039 WASHINGTON PIKE BRIDGEVILLE, PA 15017	Company Number	35900 PA 01
Chemical Name	SILVER	EPA Chemical Number	072501

Certify that:

- For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.
- That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)
☒ All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)
☐ The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form."
- That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	<i>Walter J. Polens</i>	Date	APRIL 11, 1994
Name and Title (Please Type or Print)		
WALTER J. POLENS, VICE PRESIDENT			

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	<i>Walter J. Polens</i>	Date	APRIL 11, 1994
Name and Title (Please Type or Print)		
WALTER J. POLENS, VICE PRESIDENT			



IONICS

IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE 412-343-1040 FAX 412-257-1270

EPA REREGISTRATION

PHASE 5 RESPONSE. SILVER AND COMPOUNDS
CASE NO. 4082, CHEMICAL NO. 072501

EPA REG. NO. 35900-2 (MANUFACTURING USE PRODUCT)

HYGENE BACTERIOSTATIC WATER FILTER MEDIA

ENCLOSED

- (1) OUR COMPLETED APPLICATION FOR REGISTRATION EPA FORM 8570-1
- (2) COMPLETED CONFIDENTIAL STATEMENT OF FORMULA EPA FORM 8570-4
- (3) COMPLETED CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS EPA FORM 8570-31
- (4) FIVE (5) COPIES OF OUR REVISED DRAFT LABEL AND LABELING
- (5) PRODUCT QUALITY CONTROL PROCEDURE USED TO DETERMINE THE PERCENTAGE OF THE ACTIVE INGREDIENT SILVER. LABEL CLAIM PERCENTAGE IN THIS PRODUCT IS A NOMINAL CONCENTRATION AS REQUIRED BY THE AGENCY.

2525

		United States Environmental Protection Agency Office of Pesticide Programs (H7605C) Washington, DC 20460		Registration Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number <div style="font-size: 24px; font-weight: bold;">203034</div>
Section I					
1. Company/Product Number <div style="font-weight: bold;">35900-2</div>		2. EPA Product Manager <div style="font-weight: bold;">JOHN H. LEE</div>		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) HYGENE BACTERIOSTATIC WATER FILTER MEDIA		PMs <div style="font-weight: bold;">31</div>			
5. Name and Address of Applicant (Include ZIP Code) IONICS, INCORPORATED 3039 WASHINGTON PIKE P.O. BOX 99 BRIDGEVILLE, PA 15017 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____			
Section II					
<input type="checkbox"/> Amendment - Explain below		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____			
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "Me Too" Application.			
<input type="checkbox"/> Notification - Explain below.		<input checked="" type="checkbox"/> Other - explain below.		APPLICATION FOR REREGISTRATION	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) <div style="text-align: center; padding: 10px;"> EXPEDITED AMENDMENT IN RESPONSE TO THE REREGISTRATION ELIGIBILITY DOCUMENT FOR CASE NO. 4082 SILVER AND COMPOUNDS. </div>					
Section III					
1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," Unit Package wgt. 34 LB. No. per container 1		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes," Package wgt. _____ No. per container _____	
* Certification must be submitted.		2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container <div style="font-weight: bold;">12" X 12" X 13"</div>		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed To Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other (_____)			
Section IV					
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name WALTER J. POLENS JOHN D. COLLINS		Title VICE PRESIDENT MANAGER, LABORATORY		Telephone No. (Include Area Code) <div style="font-weight: bold;">(412) 343-2040</div>	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title <div style="font-weight: bold;">VICE PRESIDENT</div>			
4. Typed Name <div style="font-weight: bold;">WALTER J. POLENS</div>		5. Date <div style="font-weight: bold;">APRIL 11, 1994</div>			

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). (If not exempted by 40 CFR 152.81 (b) (4));
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Specify the net contents of all retail containers for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Where label is affixed to product** - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.



EPA

Page 1 of 1

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved

OMB No. 2970-0107
2970-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in Ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company name and Address IONICS, INCORPORATED 3039 WASHINGTON PIKE BRIDGEVILLE PA 15017		2. Case # and Name 4082 Silver, and cmpds.		3. Date and Type of DCI PRODUCT SPECIFIC	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data 6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.		7. Product Specific Data 7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	
35900-2		N.A.	N.A.	YES	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative <i>Walter J. Polens</i>				9. Date NOVEMBER 24, 1993	
10. Name of Company Contact WALTER J. POLENS, VICE PRESIDENT				11. Phone Number 412-343-1040	

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

EPA No. 2070-0107

2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address IONICS, INCORPORATED 3039 WASHINGTON PIKE BRIDGEVILLE PA 15017	2. Case # and Name 4082 Silver, and cmpds. EPA Reg. No. 35900-2	3. Date and Type of DCI PRODUCT SPECIFIC ID# 35900-RD-3186
---	---	--

4. Guideline Requirement Number	5. Study Title	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
		1	2	3				
	<u>Prod Chem - Regular Chemical</u>							
61-1	Product identity & composition(1)				ABCDEFGHIJKLMNO	MP/EP	8 mos.	7
61-2(a)	Descrip of starting materials,(1,2) production & formulation proc				ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	7
61-2(b)	Discussion of formation of (1,3) impurities				ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	7
62-1	Preliminary analysis (1,4)				ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	7
62-2	Certification of limits (1,5)				ABCDEFGHIJKLMNO	MP/EP	8 mos.	7
62-3	Analytical method (1)				ABCDEFGHIJKLMNO	MP/EP	8 mos.	7
63-2	Color				ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	7
63-3	Physical state				ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	7
63-4	Odor				ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	7
63-5	Melting point (6)				ABCDEFGHIJKLMNO	TGAI	8 mos.	7
63-6	Boiling point (7)				ABCDEFGHIJKLMNO	TGAI	8 mos.	7
63-7	Density				ABCDEFGHIJKLMNO	MP/EP and TGAI	8 mos.	7

10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative <i>Walter J. Polens</i>	11. Date NOVEMBER 24, 1993
12. Name of Company Contact WALTER J. POLENS, VICE PRESIDENT	13. Phone Number 412-343-1040

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company name and Address IONICS, INCORPORATED 3039 WASHINGTON PIKE BRIDGEVILLE PA 15017	2. Case # and Name 4082 Silver, and cmpds. EPA Reg. No. 35900-2	3. Date and type of DCI PRODUCT SPECIFIC ID# 35900-RD-3186
---	---	--

4. Guideline Requirement Number	5. Study Title	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
63-8	Solubility	ABCDEF GHIJ KLMNO	TGAI/PAI	8 mos.	7
63-9	Vapor pressure	ABCDEF GHIJ KLMNO	TGAI/PAI	8 mos.	7
63-10	Dissociation constant	ABCDEF GHIJ KLMNO	TGAI/PAI	8 mos.	7
63-11	Octanol/water partition coefficient (8)	ABCDEF GHIJ KLMNO	PAI	8 mos.	7
63-12	pH (9)	ABCDEF GHIJ KLMNO	MP/EP and TGAI	8 mos.	7
63-13	Stability	ABCDEF GHIJ KLMNO	MP/EP	8 mos.	7
63-14	Oxidizing or reducing action (10)	ABCDEF GHIJ KLMNO	MP/EP	8 mos.	7
63-15	Flammability (11)	ABCDEF GHIJ KLMNO	MP/EP	8 mos.	7
63-16	Explosibility (12)	ABCDEF GHIJ KLMNO	MP/EP	8 mos.	7
63-17	Storage stability	ABCDEF GHIJ KLMNO	MP/EP	8 mos.	7
63-18	Viscosity (13)	ABCDEF GHIJ KLMNO	MP/EP	8 mos.	7
63-19	Miscibility (14)	ABCDEF GHIJ KLMNO	MP/EP	8 mos.	7
63-20	Corrosion characteristics	ABCDEF GHIJ KLMNO	MP/EP	8 mos.	7
63-21	Dielectric breakdown voltage (15)	ABCDEF GHIJ KLMNO	MP/EP	8 mos.	7
Acute Toxic - Regular Chemical					
81-1	Acute oral toxicity-rat (1,36,37)	ABCDEF GHIJ KLMNO	MP/EP and TGAI	8 mos.	7
81-2	Acute dermal toxicity-rabbit/rat (1,2,37)	ABCDEF GHIJ KLMNO	MP/EP and TGAI	8 mos.	7
81-3	Acute inhalation toxicity-rat (3)	ABCDEF GHIJ KLMNO	MP/EP and TGAI	8 mos.	7

Initial to indicate certification as to information on this page
(full text of certification is on page one).

Date

NOVEMBER 24, 1993

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 03-31-96

0113

ge one).

zhj

Reviewer ID

Submission No. 347 0682

Data Package No. _____

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 35900-2 PM 31Action Code 67410 Descriptor (Amend/Resubmissions only) 8 month response5 Intrastate Call-in ☐ (Y) Yes ☐ (N) No 15 Child-resistant Packaging ☐ (C) Certification☐ (S) Service Person20 Registration Type:☒ (1) Conditional ☐ (2) Unconditional☐ (R) Non-residential Use Only☐ (N) Not-Applicable25 Proposed Classification: 30 Final Classification:☐ (R) Restricted ☐ (R) Restricted☐ (G) General ☐ (N) Not Classified35 Date on Application:04 EPA Received Date:40 Date Received by PM04 06 94
MO DAY YR04 06 94
MO DAY YR04 06 94
MO DAY YR80 Method of Support:☐ (1) Cite-All ☐ (6) Owner Submission☐ (4) Not Applicable ☐ (7) Total Submission☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

DATE
SENTDUE
DATEDATE
RETURNEDRESPONSE
CODERESPONSE
DATE

CH

EF

PL

DEB

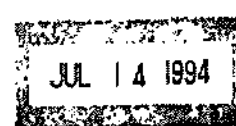
NDEB

TB

EEB

EFCB

115 FINAL Response
ACTION Code 94120 Response07 14 94
MO DAY YR75-DAY RESPONSE DUE DATE: ☐ (Y) Yes☐ (N) No



MEMORANDUM

Subject: Request to Issue a Notice of Intent to Suspend (NOITS)
to Registration of Silver Products for Failure to Respond
to the Silver RED 8-month DCI as Required under FIFRA
Section 3 (c) (2) (B).

FROM: Juanita Wills, Chief
Antimicrobial Program Branch
Registration Division (7505C)

TO: Frances Liem, Chief
Laboratory Data Integrity and Compliance Branch
Office of Enforcement and Compliance Assurance
(EN-342W)

The Antimicrobial Program Branch (APB) requests that a 3(c) (2) (B) Notice of Intent to Suspend (NOITS) be issued to those registrants of Silver products who failed to respond to the required 8-month Data Call-In (DCI) Notice in the Reregistration Eligibility Document (RED) for Silver, Case 4082.

The Silver RED required that the registrants of pesticide products containing Silver meet certain data requirements to maintain continued registration of product(s).

The registrants listed below were sent the Silver RED upon issuance August 8, 1993. As of the date of this letter, these registrants have failed to respond to the 8-month DCI. Certified mail receipt cards (green cards) were received from all registrants who were mailed the RED. Submitted as an attachment to this memo are copies of each registrants' green card showing receipt of the Silver RED document on or near August 12, 1993.

The 8-month DCI response required submission of an application for reregistration, a Confidential Statement of Formula (CSF), Certification Form, revised labeling, and submitting or citing, product-specific chemistry and acute toxicity data. Failure to adequately respond to the 8-month DCI for this RED is a basis for the Agency to issue a NOITS.

If you have any further questions regarding this matter,
please contact Karen Leavy at (703)-305-6966.

Attachments

cc: Walter Francis
Marshall Swindell

APB requests that a 3 (c) (2) (B) NOITS letter be issued to each of the registrants listed below for failure to respond to the 8-month DCI for the Silver RED. The registrants' complete name and address and registration number, is provided as follows:

- 1) Registrant: Pazianos Association
Agent For: Everpure, Inc.
1338 G Street, SE
Washington, DC 20003

EPA Reg. Nos.: 2623-4 and 2623-5

- 2) Registrant: Barnebey & Sutcliffe Corporation

EPA Reg. Nos.: 58295-1, 58295-2, and 58295-3

- 3) Registrant: BesTech, Inc.

EPA Reg. Nos.: 37589-2, 37589-4, 37589-5 and 37589-6

- 4) Registrant: Ionics, Inc.

EPA Reg. Nos.: 35900-2, 35900-3, 35900-6, 35900-7,
35900-9, 35900-12, 35900-13, 35900-16 and
35900-18

- 5) Registrant: National Safety Associates

EPA Reg. Nos.: 44751-1, 44751-2, 44751-3, 44751-4,
44751-5, 44751-7, 44751-8, 44751-9,
44751-10, and 44751-11.

3455102
Record Number

Reference Number

Input Date ☒

COODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

File Symbol/Reg. No. 35900-2 PM 31 ☒ Action Code 670

☒ [10] Descriptor (Amend/Resubmissions only) 90 DAY APPROVALS/VERIFIED DATA

☒ [3] Interstate Call-in ☐ (Y) Yes ☒ [13] Child-resistant Packaging ☐ (C) Certified ☒ (N) No ☐ (SI) Service F

☒ [20] Registration Type:

☐ (1) Conditional ☐ (2) Unconditional

☒ [23] Proposed Classification: ☒ [30] Final Classification:

☐ (R) Restricted ☐ (R) Restricted
☐ (G) General ☐ (N) Not Classified

☒ [33] Date on Application: ☒ [04] EPA Received Date: ☒ [40] Date Received by F

☒ [80] Method of Support:

☐ (1) Cite-All ☐ (6) Owner Submission
☐ (4) Not Applicable ☐ (7) Total Submission
☐ (5) Not Submitted ☐ (8) Selective Method

Reviewers Requested:

RD
PM
PL
CH
EF

DATE SENT	DUE DATE	DATE RETURNED

RESPONSE CODE	RESPONSE DATE

☒ [108] Status:

☒ [113] FINAL Response 77

☒ [120] Response 12 12 10.9.3

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

EPA No. 2070-0107
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
IONICS, INCORPORATED
3039 WASHINGTON PIKE
BRIDGEVILLE PA 15017

2. Case # and Name
4082 Silver, and cmpds.
EPA Reg. No. 35900-2

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 35900-RD-3186

4. Guideline Requirement Number	5. Study Title	6. Use Pattern	Progress Reports			7. Test Substance	8. Time Frame	9. Registrant Response
			1	2	3			
	<u>Prod Chem - Regular Chemical</u>							
61-1	Product identity & composition(1)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
61-2(a)	Descrip of starting materials,(1,2) production & formulation proc.	ABCDEFGHIJKLMNO				MP/EP and TGAI	8 mos.	7
61-2(b)	Discussion of formation of (1,3) impurities	ABCDEFGHIJKLMNO				MP/EP and TGAI	8 mos.	7
62-1	Preliminary analysis (1,4)	ABCDEFGHIJKLMNO				MP/EP and TGAI	8 mos.	7
62-2	Certification of limits (1,5)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
62-3	Analytical method (1)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
63-2	Color	ABCDEFGHIJKLMNO				MP/EP and TGAI	8 mos.	7
63-3	Physical state	ABCDEFGHIJKLMNO				MP/EP and TGAI	8 mos.	7
63-4	Odor	ABCDEFGHIJKLMNO				MP/EP and TGAI	8 mos.	7
63-5	Melting point (6)	ABCDEFGHIJKLMNO				TGAI	8 mos.	7
63-6	Boiling point (7)	ABCDEFGHIJKLMNO				TGAI	8 mos.	7
63-7	Density	ABCDEFGHIJKLMNO				MP/EP and TGAI	8 mos.	7

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative

Walter J. Polens

11. Date

NOVEMBER 24, 1993

12. Name of Company Contact

WALTER J. POLENS, VICE PRESIDENT

13. Phone Number

412-343-1040

12/1/93
Response Change / John D. Collins (JDC)

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

ONS No. 2070-0107
2070-0057

Approval Expires 03-31-96

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3039 WASHINGTON PIKE
BRIDGEVILLE PA 15017

2. Case # and Name
4082 Silver, and cmpds.
EPA Reg. No. 35900-2

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 35900-RD-3186

4. Guideline Requirement Number	5. Study Title	6. Use Pattern	Progress Reports			7. Test Substance	8. Time Frame	9. Registrant Response
			1	2	3			
63-8	Solubility	ABCDEFGHIJKLMNO				TGAI/PAI	8 mos.	7
63-9	Vapor pressure	ABCDEFGHIJKLMNO				TGAI/PAI	8 mos.	7
63-10	Dissociation constant	ABCDEFGHIJKLMNO				TGAI/PAI	8 mos.	7
63-11	Octanol/water partition coefficient (8)	ABCDEFGHIJKLMNO				PAI	8 mos.	7
63-12	pH (9)	ABCDEFGHIJKLMNO				MP/EP and TGAI	8 mos.	7
63-13	Stability	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
63-14	Oxidizing or reducing action (10)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
63-15	Flammability (11)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
63-16	Explosibility (12)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
63-17	Storage stability	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
63-18	Viscosity (13)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
63-19	Miscibility (14)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
63-20	Corrosion characteristics	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
63-21	Dielectric breakdown voltage (15)	ABCDEFGHIJKLMNO				MP/EP	8 mos.	7
<u>Acute Toxic - Regular Chemical</u>								
81-1	Acute oral toxicity-rat (1,36,37)	ABCDEFGHIJKLMNO				MP/EP and TGAI	8 mos.	7
81-2	Acute dermal toxicity-rabbit/rat (1,2,37)	ABCDEFGHIJKLMNO				MP/EP and TGAI	8 mos.	7
81-3	Acute inhalation toxicity-rat (3)	ABCDEFGHIJKLMNO				MP/EP and TGAI	8 mos.	7

Initial to indicate certification as to information on this page
(full text of certification is on page one).

Date

NOVEMBER 24, 1993

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMB No. 2070-0107
2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company name and Address

IONICS, INCORPORATED
3039 WASHINGTON PIKE
BRIDGEVILLE PA 15017

2. Case # and Name

4082 Silver, and cmpds.

EPA Reg. No. 35900-2

3. Date and Type of DCI

PRODUCT SPECIFIC
ID# 35900-RD-3186

4. Guideline Requirement Number	5. Study Title		Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
			1	2	3				
81-4	Primary eye irritation-rabbit (2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	7
81-5	Primary dermal irritation (1,2)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	7
81-6	Dermal sensitization (4)					ABCDEFGHIJKLMNO	MP/EP	8 mos.	7

Initial to indicate certification as to information on this page
(full text of certification is on page one)

Handwritten signature

Date

NOVEMBER 24, 1993

Handwritten signature

035900-00002

**IONICS**

IONICS, INCORPORATED

BRIDGEVILLE PLANT

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

**HYGENE MARK I
Bacteriostatic Water Filter Media****HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA**

- . Removes objectionable tastes, odors, and color from treated municipally supplied tap water
- . Inhibits the growth of bacteria within the filter media bed

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Mark I Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in HYgene Mark I Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a build-up or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Mark I Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.

See Reverse Side

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Hygene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS

INGREDIENTS

ACTIVE INGREDIENT

Silver (as AgNO_3) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

PACKAGING

6 Cu. Ft. Fiber Drums
1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania

Ionics, Incorporated
P.O. Box 99
Routes 519 & 50
Bridgeville, PA 15077

Attention: Walter Polens


Gentlemen:

Subject: Hygene Bacteriostatic Water Filter Media
EPA Registration No.: 35900-2
Amendment Application Date: June 12, 1981

A preliminary review of the subject application has been made. However, before the amendment can be processed further, clarification is needed in the following regard.

- (a) Please explain if 1.05% as declared on the label is that of "Silver" or is it "Silver nitrate Your label accepted October 29, 1975 declared "Metallic silver - - - 1.05%."
- (b) Is it the same product? Please clarify.
- (c) If your label declares "silver" from "silver nitrate" then you may declare no more than 0.67%. Explain why you wish to change your formulation?

Sincerely,

John H. Lee 
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)

EPA:TS-767C:JHLEE:46073:1725A:479-2018:7/6/81

Record Number 4.3421
Reference Number 2
Input Date 7-21-81

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

☐ File Symbol/Reg.No. 35900-2 ☐ PM 31 ☐ Action Code 300

5. Intrastate Call-in ☐ (Y) Yes

☒ (N) No

7. Child-resistant Packaging:

☐ (Y) Yes ☐ (N) No

8. Registration Type:

☐ (1) Conditional ☐ (2) Unconditional

9. Proposed Classification:

☐ (R) Restricted

☐ (G) General

10. Final Classification:

☐ (R) Restricted ☐ (N) Not Classified

☐ (G) General

☐ Date on Application:

16 / 12 / 81
MO DAY YR

☐ EPA Received Date:

16 / 16 / 81
MO DAY YR

☐ Date Received by PM.

16 / 17 / 81
MO DAY YR

20. Method of Support:

☐ (1) Cite-All ☐ (4) Not Applicable ☐ (1) Yes ☐ (3) Not Applicable

☐ (2) Alternate ☒ (5) Not Submitted ☒ (2) Not Submitted

☐ (3) Combined

21. Certification Statement:

☐ Reviews Requested:

RD
PM
PL
CH
EF

DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
			<u>12</u>	<u>6-26-81</u>

☐ Status:

☐ FINAL Response
ACTION: Code 12

Response
Date

07 / 16 / 81
MO DAY YR

☐ 75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

TECHNICAL SUPPORT SECTION CHEMISTRY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 35900-2

Date Division Received _____

Products Manager No. 31 (Lee)

Product Name Hygenic Mark I Bacteriostatic Water Filter Media

Company Name Ionics, Inc

1.00 Comments:

- a. Please explain if 1.05% as declared on the label is that of "Silver" or is it "Silver nitrate".
Your label accepted Oct. 29, 1975 declared
"Metallic silver . . . 1.05%."

Is it the same product? Please clarify.

If your label declares "silver" from "silver nitrate" then you may declare no more than 0.67%. Explain why you wish to change your formulation?

6-25-81 Anna Skapars

ENFORCEMENT CASE REVIEW

TO: Director, Pesticides Enforcement Division Office of Enforcement and General Counsel		I.O. NO. 172045
		EPA REGISTRATION NO. See below
PRODUCT NAME (On sample label) BON-DEL BACTERIOSTATIC WATER UNIT		
COMPANY NAME AND ADDRESS (On sample label) (Include ZIP code) Bon Del Inc. 157 S. Roseway Mesa, AZ 85202		REGISTRATION STATUS AT TIME OF xxxxxx Collection <input type="checkbox"/> REGISTERED <input checked="" type="checkbox"/> NOT REGISTERED
DISTRIBUTOR STATUS AT TIME OF SHIPMENT (If applicable)		
BASIC PRODUCT NAME		PRODUCT SUPPLEMENTALLY REGISTERED <input type="checkbox"/> YES <input type="checkbox"/> NO
TRANT NAME AND ADDRESS (Include ZIP code)		DATE OF SUPPLEMENTAL REGISTRATION
OTHER PERTINENT REGISTRATION DATA <p> "The "Bacteriostatic Water Filter Media" which is used in the BON-DEL BACTERIOSTATIC WATER UNIT is registered to MONICS, Inc., P.O. Box 99, Bridgeville, PA. 15017 for product name HYGENE under EPA Reg. No. 35900-2. </p> <p> Bon Del Inc., Mesa, AZ 85202 (company number 43430) is not supplementally registered under EPA Reg. No. 35900-2. They have no registered products. They have three applications pending (1) 43430-F for BON DEL MODEL R-1, (2) 43430-E for BON DEL MODEL T-1, (3) 43430-G for BON DEL MODEL CT-5 (all applications dated 10-16-79). </p>		
IS THIS A PESTICIDE? <input checked="" type="checkbox"/> YES (If yes, list claims below) <input type="checkbox"/> NO		
PESTICIDE CLAIMS <p> <i>when dispersed in water</i> <i>it destroys bacteria</i> <i>it is used in water supply for</i> <i>home use, etc.</i> </p>		
SIGNATURE OF BRANCH CHIEF (Registration Div., Office of Pesticides Programs) Edward L. Bush Enforcement Coordinator - Registration		DATE 1/15/79

RECORD OF TELEPHONE CALL OR VISITOR		DATE
INCOMING CALL <input checked="" type="checkbox"/>	OUTGOING CALL <input checked="" type="checkbox"/>	VISITOR <input type="checkbox"/>
NAME OF PERSON		9/12/79
NAME & ADDRESS OF COMPANY		COMPANY TEL. NO. (Include Area Code)
Utah Dept. of Health		801/533/6121
		REGISTRATION NO. OR FILE SYMBOL
		DATE OF LATEST SUBMISSION

BRIEF SUMMARY OF CONVERSATION

Questions About H₂O Purifier

① - Is Bax Del H₂O Purifier Registered? - NO -

It says it uses "EPA Registered Media 35900-2" ~~to use~~ in it. Has other Number 35900 - PA 01 Prob. Estab #


② - Does it have to be Registered? Yes.

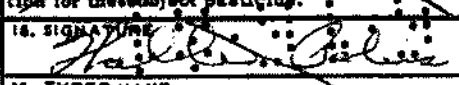
ACTION TAKEN


There are a "lot of people" with a "lot of money" in this.

If you have other questions (about Enforcement etc.) you should contact A.E. Canray (Enforcement) for more info. Will do.

RECORDED BY (Name)	REFERRED TO (Name)
E. HP	

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDE PROGRAMS (WP-167) WASHINGTON, D.C. 20460		1. REFERENCE CODE	2. EPA USE ONLY
APPLICATION FOR AMENDED PESTICIDE PRODUCT REGISTRATION (Read instructions on last page before completing) B		3. REGISTRATION NO. 35900-2	4. PRODUCT MANAGER John H. Lee
5. NAME AND ADDRESS OF REGISTRANT (Include Zip Code) Ionics, Incorporated P.O. Box 99 Routes 519 & 50 Bridgeville, PA 15017 <input type="checkbox"/> CHECK HERE IF THIS IS A NEW ADDRESS		6. TYPE OF AMENDMENT <input checked="" type="checkbox"/> CHANGE IN PRODUCT NAME <input type="checkbox"/> MINOR CHANGE IN FORMULATION <input type="checkbox"/> REQUEST FOR ADDITIONAL BRAND NAMES <input type="checkbox"/> REQUEST FOR MULTIPLE INERT FORMULATION PER PR NOTICE 79-2 <input type="checkbox"/> DELETION OF LABEL TEXT <input type="checkbox"/> ADDED USES (without data) <input type="checkbox"/> ADDED USES (with data) <input checked="" type="checkbox"/> GENERAL REVISION OF LABEL	
7. PRODUCT NAME HYgene Mark I Bacteriostatic Water Filter Media		8. EXPERIMENTAL PERMIT NO.	
9. SUBJECT OF AMENDMENT (See instructions) Change product name from HYgene Bacteriostatic Water Filter Medium to above (7) product name. General revision of label to meet current regulations.			
12. TYPES OF DATA SUBMITTED		FOR EPA USE ONLY	
<input checked="" type="checkbox"/> 01 NONE		1201	
<input type="checkbox"/> 02 PRODUCT CHEMISTRY		1202	
<input type="checkbox"/> 03 RESIDUE CHEMISTRY		1203	
<input type="checkbox"/> 04 ENVIRONMENTAL CHEMISTRY		1204	
<input type="checkbox"/> 05 EFFICACY		1205	
<input type="checkbox"/> 06 PHYTOTOXICITY		1206	
<input type="checkbox"/> 07 HUMAN SAFETY		1207	
<input type="checkbox"/> 08 DOMESTIC ANIMAL SAFETY		1208	
<input type="checkbox"/> 09 FISH AND WILDLIFE SAFETY		1209	
<input type="checkbox"/> 10 BENEFICIAL INSECT SAFETY		1210	
<input type="checkbox"/> 11 ACCIDENT EXPOSURE EXPERIENCE		1211	
<input type="checkbox"/> 12 OTHER (Specify)		1212	
<input type="checkbox"/> 13 OTHER (Specify)		1213	
13. METHOD OF SUPPORT (See instructions) <input type="checkbox"/> Required Supporting Data Attached. (2A) <input checked="" type="checkbox"/> Required Supporting Data is Submitted by Reference. (2B) <input type="checkbox"/> Proceed on the Basis of Established-Use Patterns. (2C)		14. CONTACT POINT Complete items directly below for identification of individual to be contacted, if necessary, to process this application.	
OFFER TO PAY STATEMENT I hereby offer to pay reasonable compensation to the extent provided under Section 3 (c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and in accordance with the Regulations and Guidelines published thereunder for use of any test data which has been submitted to the U.S. Environmental Protection Agency in connection with an application for the registration of a pesticide for the first time on or after October 21, 1972 and which may be used in support of the registration application for the subject pesticide....		NAME Walter J. Polens	
		TITLE Vice President	
		TELEPHONE NO. (Include Area Code) (412) 343-1040	
16. SIGNATURE 		17. TITLE U.P.	
18. TYPE NAME Walter J. Polens		19. DATE SIGNED 6/12/81	

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDE PROGRAMS (WPP-567) WASHINGTON, D.C. 20460 APPLICATION FOR <u>AMENDED</u> PESTICIDE PRODUCT REGISTRATION (Read instructions on last page before completing) B		1. REFERENCE CODE 3. REGISTRATION NO. 35900-2	2. STATUS [REDACTED] 4. PRODUCT MANAGER John H. Lee
3. NAME AND ADDRESS OF REGISTRANT (Include Zip Code) Ionics, Incorporated P.O. Box 99 Routes 519 & 50 Bridgeville, PA 15017 <input type="checkbox"/> CHECK HERE IF THIS IS A NEW ADDRESS		5. TYPE OF AMENDMENT <input checked="" type="checkbox"/> CHANGE IN PRODUCT NAME <input type="checkbox"/> MINOR CHANGE IN FORMULATION <input type="checkbox"/> REQUEST FOR ADDITIONAL BRAND NAMES <input type="checkbox"/> REQUEST FOR MULTIPLE INERT FORMULATION PER PR NOTICE 79-2 <input type="checkbox"/> DELETION OF LABEL TEST <input type="checkbox"/> ADDED USES (without data) <input type="checkbox"/> ADDED USES (with data) <input checked="" type="checkbox"/> GENERAL REVISION OF LABEL	
7. PRODUCT NAME HYgene Mark I Bacteriostatic Water Filter Media		6. EXPERIMENTAL PERMIT NO.	
9. SUBJECT OF AMENDMENT (See instructions) Change product name from HYgene Bacteriostatic Water Filter Medium to above (7) product name. General revision of label to meet current regulations.			
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16. SIGNATURE 		NAME Walter J. Polens	
17. TYPED NAME Walter J. Polens		TITLE Vice President	
18. DATE SIGNED 6/12/81		TELEPHONE NO. (Include Area Code) (412) 343-1040	

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDE PROGRAMS (70-547) WASHINGTON, D.C. 20460 APPLICATION FOR <u>AMENDED</u> PESTICIDE PRODUCT REGISTRATION (Read instructions on last page before completing) B		1. REFERENCE CODE 2. REGISTRATION NO. 35900-2		3. PRODUCT NAME John H. Lee																																																																																																																																																																																																					
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IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5108973299

June 10, 1981

Mr. John H. Lee, Product Manager 31
Disinfectants Branch
Registration Division (TS-767)
U. S. Environmental Protection Agency
401 M Street S. W.
Washington, D. C. 20460

SUBJECT: Application for Amended Pesticide Product Registration
for Registration No. 35900-2

Dear Mr. Lee:

Enclosed with this letter you will find our "Application for Amended Pesticide Product Registration", your Form 8570-11. The amendment is because of change of product name from HYgene Bacteriostatic Water Filter Media to HYgene Mark I Bacteriostatic Water Filter Media. General revisions of label also to meet current regulations. We have also enclosed your Form 8570-4 "Confidential Statement of Formula" along with five final printed labels. Five copies of our revised Product Data Sheet are enclosed which show these changes.

This change does not affect the efficacy and safety of use of this product.

Your early consideration of this amended registration will be very much appreciated.

Very truly yours,

IONICS, INCORPORATED

Walter J. Polens
Vice President

WJP:mle

Enclosures
10319

4443

HYgene Mark I

BACTERIOSTATIC WATER FILTER MEDIA

Removes objectionable tastes, odors, color from treated municipally—supplied tap water.

Inhibits the growth of bacteria within the filter media bed.

CAUTION: KEEP OUT OF REACH OF CHILDREN

EPA Reg. No. 35900—2 EPA Est. No. 35900 PA. 01.

ACTIVE INGREDIENT

SILVER as Ag NO_3 ----- 1.05 % LOT No. _____

INERT INGREDIENT

ACTIVATED CARBON---98.95 % NET CONTENTS _____cu. ft.

STORAGE-----Store in closed container which excludes moisture and fumes.

DIRECTIONS FOR USE-----Refer to enclosed product data sheet.

DISPOSAL OF SPENT MEDIA---Retain Shipping carton and liner for disposing of exhausted filter media with trash.

USE-----This product is to be used only for manufacturing or fabricating Bacteriostatic Water Filter Products for home use.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment.

IONICS, INC. Routes 519 & 50 P.O. Box 99 Bridgeville, Pa. 15017

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS

INGREDIENTS

ACTIVE INGREDIENT

Silver (as AgNO_3) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

PACKAGING

6 Cu. Ft. Fiber Drums
1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania

**IONICS**

IONICS, INCORPORATED

BRIDGEVILLE PLANT

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE MARK I
Bacteriostatic Water Filter Media**HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA**

- Removes objectionable tastes, odors, and color from treated municipally supplied tap water
- Inhibits the growth of bacteria within the filter media bed

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Mark I Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in HYgene Mark I Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a build-up or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Mark I Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.

See Reverse Side

**IONICS**

IONICS, INCORPORATED

BRIDGEVILLE PLANT

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

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See Reverse Side

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS

INGREDIENTS

ACTIVE INGREDIENT

Silver (as AgNO_3) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

PACKAGING

6 Cu. Ft. Fiber Drums
1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

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SHIPPING POINT

Bridgeville, Pennsylvania

**IONICS****IONICS, INCORPORATED**
BRIDGEVILLE PLANT

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE MARK I
Bacteriostatic Water Filter Media**HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA**

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- . Inhibits the growth of bacteria within the filter media bed

WHAT IT IS AND HOW IT WORKS

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See Reverse Side

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

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Bridgeville, Pennsylvania

**IONICS**

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BRIDGEVILLE PLANT

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Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in HYgene Mark I Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a build-up or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Mark I Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.

See Reverse Side

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Hygene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS

INGREDIENTS

ACTIVE INGREDIENT

Silver (as AgNO_3) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

PACKAGING

6 Cu. Ft. Fiber Drums
1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

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1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania

**IONICS**

IONICS, INCORPORATED

BRIDGEVILLE PLANT

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE MARK I
Bacteriostatic Water Filter MediaHYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA

- . Removes objectionable tastes, odors, and color from treated municipally supplied tap water
- . Inhibits the growth of bacteria within the filter media bed

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Mark I Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in HYgene Mark I Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

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The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

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See Reverse Side

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SPECIFICATIONS

INGREDIENTS

ACTIVE INGREDIENT

Silver (as AgNO_3) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

PACKAGING

6 Cu. Ft. Fiber Drums
1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

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Silver (as AgNO_3) - 1.05%

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12 x 30 U.S. Sieve Series

PACKAGING

6 Cu. Ft. Fiber Drums
1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania

SUBMISSION REVIEW RECORD			1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED			
3. 3CID PUBLICATION NECESSARY <input type="checkbox"/> YES <input type="checkbox"/> NO			4. PETITION NO.					5. RECEIVED PM TEAM			
6. METHOD OF SUPPORT <input type="checkbox"/> 2A <input type="checkbox"/> 2B <input type="checkbox"/> 2C			7. PRODUCT MANAGER				NO.	8. PROJECTED RETURN			
9. DATE PULLED		10. DATE PUBLISHED		11. ACTION TYPE				CODE	12. OUTGOING DATE		
REV. SEQ.	REVIEW TYPE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER			COM-MENT CODE	DATE REVIEW COMPLETED			
	A	REVIEWABILITY TEAM						MO	DAY	YR	
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW									
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW									
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW									
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW									
	F	PRODUCT MANAGER									
	G	INTERAGENCY REFERRAL									
	H	COST-BENEFIT REVIEW									
	I	PUBLIC COMMENTS REVIEW									
	J	EEE BRANCH INSECTICIDE EFFICACY									
	K	EEE BRANCH HERBICIDE EFFICACY									
	L	EEE BRANCH FUNGICIDE EFFICACY									
	M	EEE BRANCH RODENTICIDE EFFICACY									
	N	EEE BRANCH DISINFECTANT EFFICACY									
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY									
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY									
	Q	TOXICOLOGY BRANCH HUMAN SAFETY									
	R	EEE BRANCH ENVIRONMENTAL SAFETY									
	S										
	T										
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE				CODE			

IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

July 30, 1979

Dear [REDACTED]

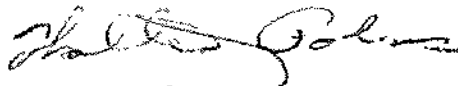
This letter will confirm our telephone conversation of July 30th in reference to your offer to commence negotiations to determine compensation for using the data in our files under EPA Reg. No. 35900-2 to register your water filter under the Federal Insecticide/Fungicide/Rodenticide Act.

We would be pleased to allow the EPA to refer to this data in our files but not to show this to you as this is proprietary information and classified "Confidential". We would, however, agree that since [REDACTED]

We look forward to receiving your reply.

Very truly yours,

IONICS, INCORPORATED



Walter J. Polens
Vice President

WJP:mle

cc: J. D. Collins - Ionics
E. Brown - EPA
J. Banks - EPA
J. Lee - EPA

629 9

8443

IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

July 30, 1979

Dear [REDACTED]

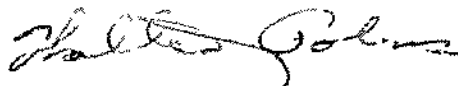
This letter will confirm our telephone conversation of July 30th in reference to your offer to commence negotiations to determine compensation for using the data in our files under EPA Reg. No. 35900-2 to register your water filter under the Federal Insecticide/Fungicide/Rodenticide Act.

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We look forward to receiving your reply.

Very truly yours,

IONICS, INCORPORATED



Walter J. Polens
Vice President

WJP:mle

cc: J. D. Collins - Ionics
E. Brown - EPA
J. Banks - EPA
J. Lee - EPA

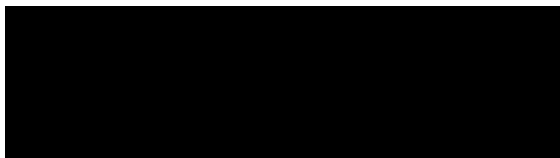
9333



IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

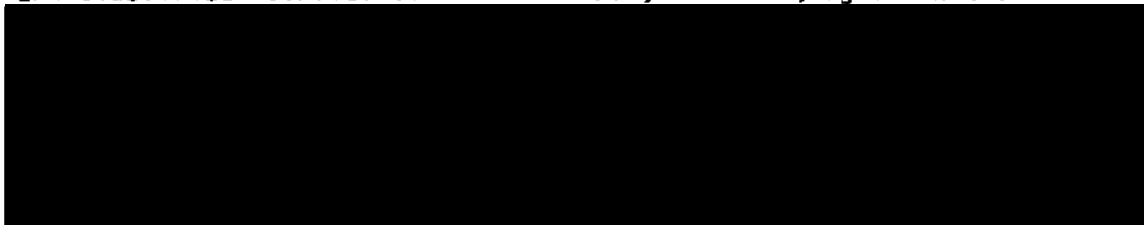
July 30, 1979



Dear 

This letter will confirm our telephone conversation of July 30th in reference to your offer to commence negotiations to determine compensation for using the data in our files under EPA Reg. No. 35900-2 to register your water filter under the Federal Insecticide/Fungicide/Rodenticide Act.

We would be pleased to allow the EPA to refer to this data in our files but not to show this to you as this is proprietary information and classified "Confidential". We would, however, agree that since



We look forward to receiving your reply.

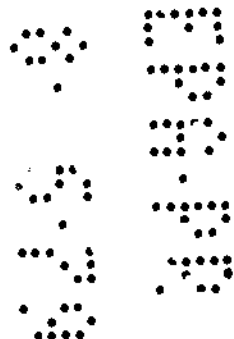
Very truly yours,

IONICS, INCORPORATED

Walter J. Polens
Vice President

WJP:mle

cc: J. D. Collins - Ionics
E. Brown - EPA
J. Banks - EPA
J. Lee - EPA



ENFORCEMENT CASE REVIEW

TO: Director, Pesticides Enforcement Division Office of Enforcement and General Counsel		I.D. NO. 131823 EPA REGISTRATION NO. 35900-2
PRODUCT NAME (On sample label) BON DEL BACTERIOSTATIC WATER FILTER		
COMPANY NAME AND ADDRESS (On sample label) (Include ZIP code) Bon Del, Inc. 2605 East Geneva Drive Tempe, AZ 85282		REGISTRATION STATUS AT TIME OF SHIPMENT <input checked="" type="checkbox"/> REGISTERED <input type="checkbox"/> NOT REGISTERED
DISTRIBUTOR STATUS AT TIME OF SHIPMENT (If applicable)		
BASIC PRODUCT NAME HYGENE		PRODUCT SUPPLEMENTALLY REGISTERED <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
DISTRANT NAME AND ADDRESS (Include ZIP code) Ionics, Inc. P.O. Box 99 Bridgeville, PA 15017		DATE OF SUPPLEMENTAL REGISTRATION
OTHER PERTINENT REGISTRATION DATA <p>A company number has not been assigned to Bon Del Inc., 2605 East Geneva Drive, Tempe AZ 85282.</p> <p>The filter is registered. However, the three models (Counter-Top, Portable and Refrigerator) are not registered.</p>		
IS THIS A PESTICIDE? <input checked="" type="checkbox"/> YES (If yes, list claims below) <input type="checkbox"/> NO		
PESTICIDE CLAIMS		
SIGNATURE OF BRANCH CHIEF (Registration Div., Office of Pesticides Programs) Edward L. Bunch Enforcement Coordinator - Registration		DATE 5/15/79

ENFORCEMENT CASE REVIEW (Test and Label)				ID NUMBER <div style="font-size: 1.2em;">131823</div>	
				EPA REGISTRATION NUMBER <div style="font-size: 1.2em;">NONE</div>	
TYPE OF REVIEW					
CHEMISTRY	<input checked="" type="checkbox"/> EFFICACY	<input type="checkbox"/> SAFETY	OTHER (Specify)		
TEST RESULTS AND SIGNIFICANCE					
<ol style="list-style-type: none"> 1. No directions to assure the adequate use of the types of water filters, identified as "Counter-top model", "portable model" and "refrigerator model", were included in the sample labeling. 2. The pesticidal claim "destroys all bacteria" exceeds the level of effectiveness demonstrated for the silver-impregnated water filter media, "Hygen", incorporated in these water treatment devices. 3. The collateral literature, "Medical Tribune" gives a false or misleading impression to the purchaser that the sample water filter products will be effective in eliminating pollutants 					
LABELING REVIEW					
ARE THERE ANY SIGNIFICANT LABELING DEFECTS? <input type="checkbox"/> YES (If yes, list substantial discrepancies and significances below)					<input type="checkbox"/> NO
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES <div style="font-size: 1.2em;">from drinking water:</div>					<div style="text-align: right;"> <div style="font-size: 1.2em;">7/30/79</div> <div style="font-size: 1.2em;">DM Porter</div> <div style="font-size: 1.2em;">microbiologist</div> </div>

ENFORCEMENT CASE REVIEW <i>(Test and Label)</i>		ID NUMBER 131823	
		EPA REGISTRATION NUMBER 35900-2	
TYPE OF REVIEW			
<input checked="" type="checkbox"/> CHEMISTRY	<input checked="" type="checkbox"/> EFFICACY	<input checked="" type="checkbox"/> SAFETY	OTHER (Specify)
TEST RESULTS AND SIGNIFICANCE <div style="font-family: cursive; font-size: 1.2em;"> No report of chemical analysis, documentary sample </div>			
LABELING REVIEW			
ARE THERE ANY SIGNIFICANT LABELING DEFECTS? <input checked="" type="checkbox"/> YES (If yes, list substantial discrepancies and significances below)			<input type="checkbox"/> NO
			DATE OF ACCEPTANCE OF APPLICABLE LABELING <div style="font-family: cursive; font-size: 1.2em;">10/29/75</div>
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES <div style="font-family: cursive; font-size: 1.2em;"> Comments by Dorothy Portner, a copy of the accepted label is attached for your information. </div> <div style="text-align: right; margin-top: 20px;"> <div style="font-family: cursive; font-size: 1.2em;">E. Benich</div> <div style="font-size: 1.2em;">8/15/79</div> </div>			

ENFORCEMENT CASE REVIEW

TO: Director, Pesticides Enforcement Division Office of Enforcement and General Counsel		I.D. NO. EC-79-28
		EPA REGISTRATION NO. 35900-2
PRODUCT NAME (On sample label) BON DEL BACTERIOSTATIC WATER UNIT		
COMPANY NAME AND ADDRESS (On sample label) (Include ZIP code) Bon Del, Inc. 2605 East Geneva Drive Tempe, AZ 85282		REGISTRATION STATUS AT TIME OF SHIPMENT xxxxxx Collection <input checked="" type="checkbox"/> REGISTERED <input type="checkbox"/> NOT REGISTERED
DISTRIBUTOR STATUS AT TIME OF SHIPMENT (If applicable)		
BASIC PRODUCT NAME HYGENE		PRODUCT SUPPLEMENTALLY REGISTERED <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
SUPPLIER NAME AND ADDRESS (Include ZIP code) Ionics, Inc. P.O. Box 99 Bridgeville, PA 15017		DATE OF SUPPLEMENTAL REGISTRATION
OTHER PERTINENT REGISTRATION DATA A company number has not been assigned to Bon Del Inc., 2605 East Geneva Drive, Tempe, AZ 85282.		
IS THIS A PESTICIDE? <input checked="" type="checkbox"/> YES (If yes, list claims below) <input type="checkbox"/> NO		
PESTICIDE CLAIMS		
SIGNATURE OF BRANCH CHIEF (Registration Div., Office of Pesticides Programs) <i>Edward L. Bunch</i> for Edward L. Bunch Enforcement Coordinator - Registration		DATE 5-31-79

ENFORCEMENT CASE REVIEW <i>(Test and Label)</i>			ID NUMBER <div style="font-size: 1.2em; font-family: cursive;">EC-79-28</div>	
			EPA REGISTRATION NUMBER <div style="font-size: 1.2em; font-family: cursive;">35900-2</div>	
TYPE OF REVIEW				
<input checked="" type="checkbox"/> CHEMISTRY	<input type="checkbox"/> EFFICACY	<input type="checkbox"/> SAFETY	<input type="checkbox"/> OTHER (Specify)	
TEST RESULTS AND SIGNIFICANCE <div style="font-size: 1.5em; font-family: cursive; text-align: center;">No Analysis performed</div>				
LABELING REVIEW				
ARE THERE ANY SIGNIFICANT LABELING DEFECTS? <input checked="" type="checkbox"/> YES (If yes, list substantial discrepancies and significances below)			<input type="checkbox"/> NO	
			DATE OF ACCEPTANCE OF APPLICABLE LABELING <div style="font-size: 1.2em; font-family: cursive;">10-29-75</div>	
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES <div style="font-size: 1.5em; font-family: cursive; text-align: center;">See D.M. Portner's review</div> <div style="text-align: right; margin-top: 50px;"> <div style="font-size: 1.2em; font-family: cursive;">B. Schwallen</div> <div style="font-size: 1.2em; font-family: cursive;">5-31-79</div> </div>				

ENFORCEMENT CASE REVIEW (Test and Label)		ID NUMBER EC-79-28	
		EPA REGISTRATION NUMBER None	
TYPE OF REVIEW			
CHEMISTRY	<input checked="" type="checkbox"/> EFFICACY	SAFETY	OTHER (Specify)
TEST RESULTS AND SIGNIFICANCE			
<p>The following claims on the labeling are considered under the provisions indicated in Section 162.10 (a) (5) of the Regulations for Enforcement of FIFRA as false and misleading statements:</p> <ol style="list-style-type: none"> 1. The pesticidal claims for disinfecting water and killing 100% bacteria exceed the effectiveness of the silver impregnated water filter media, "Hygon", incorporated in this water treatment device. 2. The non-pesticidal claims for removal of "Insecticides such as 1. Chlorlure ... 9. Toxaphene", "Industrial chemicals and solvents such as 1. Acetophenone ... 7. propylene chlorohydrin", "specific inorganic found in water such as 2. Arsenic ... 5. Mercury" and the value of this water filter media for such purposes. 3. The claim "The applications, testing and performance of the media" 			
LABELING REVIEW			
ARE THERE ANY SIGNIFICANT LABELING DEFECTS? <input type="checkbox"/> YES (If yes, list substantial discrepancies and significances below)			<input type="checkbox"/> NO DATE OF ACCEPTANCE OF APPLICABLE LABELING
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES			
<p>has been approved by the Environmental Protection Agency (EPA # 35400-2) implies recommendation or endorsement by EPA.</p> <ol style="list-style-type: none"> 4. Articles from Grand Home Keeping, Empire, Phoenix Gazette, Mass Tribune and other newspapers, which accompanied the sample labeling, give a false or misleading impression to the purchaser that the sample product will be effective in eliminating the pollutants from drinking water. 5. The sample label bears the EPA Registration number for the water filter media used in this device, but no EPA Registration number for the pesticidal device itself. 			
D M Porter Microbiologist 5-30-79			BSH



IONICS
IONICS, INCORPORATED

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A.C. 412 343-1040 TWX 5106973299

January 13, 1977

Mr. E. F. Brown
Chief, Disinfectants Branch
Registration Division (WH-567)
U. S. Environmental Protection Agency
401 M Street S. W.
Washington, D. C. 20460

Dear Mr. Brown:


This letter will authorize you to use any information that is in Ionics, Incorporated's file, our EPA Registration 35900-2, to support registration of additional products for [REDACTED]

This letter does not, however, allow you to make public to [REDACTED] or anyone else any information in our file that would be considered proprietary information or confidential.

We thank you very much for your cooperation in this matter.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant


Walter J. Polens
Vice President

WJP:mle

cc: James H. Banks - EPA

[REDACTED]
J. D. Collins - Ionics

PM 33

*Please place in
EPA Reg No. 35900-2*

*Brown,
1/2*

IONICS, INCORPORATED
Attn: Walter J. Polens
P.O. Box 99
Bridgeville, PA 15017

Dear Mr. Polens:

This is to acknowledge receipt of your letter of June 22, 1976 regarding the Volhard Method of Analysis. According to your letter it is our understanding that the Atomic Absorption Method of Analysis is being used by you or your agent(s) to analyze the "Hypene Bacteriostatic Water Filter Media" for silver content rather than the Volhard Method of Analysis. If our understanding of this matter is incorrect, please correct us.

Sincerely,

James H. Banks
Product Manager 33
Disinfectants Branch
Registration Division (WH-567)

WH-567:DIS:RGD:md:59040:Rm 321 12/17/76



IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

35900-2

June 22, 1976

Mr. James H. Banks, Product Manager 33
Disinfectants Branch (WH-567)
Registration Division
U. S. Environmental Protection Agency
401 M Street S. W.
Washington, D. C. 20460

SUBJECT: Volhard Method of Analysis

Dear Mr. Banks:

This is in reply to your letter of June 1, 1976 in reference to the Volhard Method for the determination of silver.

Silver Analyses in conjunction with our HYgene product testing for EPA are run at NUS Corporation, Cyrus Wm. Rice Division. We have been advised by Mrs. Linda Deans, Manager of Analytical Services at NUS that the Volhard Method is not presently being used in their laboratory for silver analysis. According to Mrs. Deans and several other reliable sources we have contacted concerning this subject, the Atomic Absorption Method is considered much more accurate than the Volhard Method not only in the trace quantity (ppb) range but also in the high silver concentration (ppm) range.

If there are any further questions in this regard, please advise us.

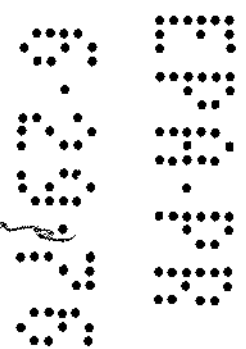
Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle

cc: J. O. Collins - Ionics



REGISTRATION DIVISION

JUN 01 1976

IONICS, INC.
Attn: Walter J. Polens
P.O. Box 99
Bridgeville, PA 15017

Gentlemen:

Subject : LETTER OF May 11, 1976

The information submitted with your letter of May 11, 1976 regarding the Atomic Absorption Method of Analysis is acceptable. However, in order to satisfy the general chemistry data requirements, you must submit details of the Volhard Method of Analysis as also requested in our letter of April 28, 1976.

Sincerely,

James H. Banks *JHB*
Product Manager 33
Disinfectants Branch (WH-567)

WH-567:DIS:RGD:md:59040:Rm 321

5/28/76



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

35900-2

May 11, 1976

Mr. James H. Banks, Product Manager 33
United States Environmental Protection Agency
Disinfectants Branch (WH-567)
Registration Division
401 M Street S. W.
Washington, D. C. 20640

Ref: Your Letter Stamped April 28, 1976

Dear Mr. Banks:

Enclosed with this letter is a copy of a letter we received from NUS Corporation which gives the details of the Atomic Absorption Method of Analysis. This should satisfy your general chemistry data that you requested.


I appreciate receiving the information on the progress of our submission of December 5, 1975 in reference to Pool Gene and we will look forward to receiving the completed report within the next few weeks.

I have also enclosed with this letter a copy of my letter of February 18, 1976 in which I requested status on our Food Additive Petition No. 5H5079. I have heard nothing at all about this. I would appreciate a reply as soon as possible.

Thank you very much for your cooperation in this matter.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant


Walter J. Polens
Vice President

WJP:mle

Enclosures (2)

92079

84443

Quality control process information may be entitled to confidential treatment

February 18, 1976

Mr. James H. Banks, Product Manager 33
United States Environmental Protection Agency
Disinfectants Branch (WH-567)
Registration Division
401 M Street S.W.
Washington, D. C. 20640

Dear Mr. Banks:

Would you please inform me of the status of our Food Additive
Petition No. 5H5079 which was sent to you on February 10, 1975 and which
you informed us was being filed on March 27, 1975.

Your prompt attention to the above will be very much appreciated.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle

92079

44843

EPA Form 8570-13 (3-75)

EPA Form 8870-12 (2-75)

EEE BRANCH REVIEW

DATE: IN _____ OUT _____ IN _____ OUT _____ IN 8/24 OUT 8/27/76
FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. _____
PETITION OR EXP. PERMIT NO. FAP #5H5079
DATE DIV. RECEIVED 6-23-76
DATE OF SUBMISSION 6-17-76
DATE SUBMISSION ACCEPTED _____
TYPE PRODUCT(S): I, (D) H, F, N, R, S Bacteriostatic Water Filter Media
PRODUCT MGR. NO. 33
PRODUCT NAME(S) Hygene Bacteriostatic Water Filter Media
COMPANY NAME Ionics, Inc.
SUBMISSION PURPOSE Resubmission with data
CHEMICAL & FORMULATION Metallic silver - - - 1.05%

200.0 Introduction

200.1 Use: Bacteriostatic Water Filter Media

201.0 Data Summary Background Information

The bacteriological data originally submitted with this petition were also submitted with the application for registration of this product. These data were not acceptable to support efficacy of this product as a water purifier (to render raw water microbiologically potable) as indicated in our letter of July 25, 1975.

The data included in the submission of June 17, 1976 for this petition have been accepted to substantiate bacteriostatic activity for the water filter media itself.

202.0 Recommendations

202.2 Claims not supported by data submitted:

The bacteriological efficacy data submitted originally in conjunction with both this petition and the application for registration were unacceptable as indicated in our letter of July 25, 1975.

The data submitted with your letter of June 17, 1976 will not support the claim that less than 50 ppb silver in the water is at an efficacious level to render raw water microbiologically potable. These data were accepted to substantiate bacteriostatic activity for the water filter media itself which is used in housing devices to further process municipally treated tap water by removing undesirable tastes and odors. The silver is an incidental food additive in the tap water so processed.

Since the review of a food additive petition for silver is based on data requirements for residues from a disinfectant to render raw water potable rather than an incidental food additive in tap water caused by leaching of the bacteriostatic used to prolong the life of the filter media, a new petition should be filed to reflect the intended use pattern.

202.3 Additional data required: Because the performance of the water filter media will vary according to the quality of the tap water, the silver tolerance of 50 ppb should be based on data developed with quality parameters which would cause the maximum leaching of silver into the effluent tap water that could be encountered under use conditions. Note the quality parameters defined in the "Interim Requirements for Registration of Bacteriostatic Water Treatment Units for Home Use" (Federal Register, Vol. 41, No. 152, p. 3277B-32782, Thursday, August 5, 1976), are:

pH: 6-8
Hardness as CaCO_3 : 25 mg/l (ppm)
Alkalinity as CaCO_3 : 20 mg/l (ppm)
Total Dissolved Solids: 10-40 mg/l (ppm)
Temperature: 20°-25°C

The chemical analysis for the tap water used to develop the data submitted indicated that these water quality parameters were not fully met.

203.0 Labeling

The following revisions are required to reflect this product as a bacteriostatic water filter as claimed:

1. Revise the claim "Do not use in combination with other silver disinfecting devices, e.g., silver filters" to read "Do not use other silver-impregnated filter media in combination with Hygene Bacteriostatic Water Filter Media to fabricate or manufacture water treatment products".
2. Revise the claim "raw water limitations" to read "tap water limitations".
3. Delete "and at an efficacious level".
4. Indicate that fabricators or manufacturer of water treatment products are responsible for providing data to support their registration.
5. Clarify the function of the silver in the water filter media somewhat as follows: "Silver is incorporated into this water filter media to inhibit the growth of bacteria entrapped in the media when municipal treated water is filtered."
6. Identify the claim "Flow rate is not to exceed..." as "Directions for Use".
7. On the product label, clarify the claim "Inhibits the growth of bacteria" to read "Inhibits the growth of bacteria in the filter media".
8. On the product label, indicate that the product is to be used only for fabricating or manufacturing water treatment products.

Dorothy M. Portner

Dorothy M. Portner 8/27/76
Efficacy Section
Efficacy and Ecological Effects Branch



UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

REPORT OF ANALYSIS

1. SAMPLE NO.
112876

2. DATE COLLECTED
3-23-76

3. REGION
III

SAMPLE IDENTIFICATION

4. LOT OR CODE NO(S). 03226B		5. EPA REGISTRATION NO. 35900-2	6. ESTABLISHMENT NO. 35900-PK-01
7. PRODUCT NAME "HYGENE Bacteriostatic Water Filter Media"			
8. PRODUCER NAME AND ADDRESS (Include ZIP code) IONICS, INC. Routes 519 and 50 Bridgeville, Penna. 15017		9. DEALER NAME AND ADDRESS (Include ZIP code)	
10. PHYSICAL FORM	EMULS. CONC. WET. POWDER	PRESS. SPRAY AEROSOL	DUST BAIT
			<input checked="" type="checkbox"/> GRANULAR OTHER

11. INGREDIENTS

Silver (Metallic) 1.05%
Activated Carbon 98.95%

TEST

12. TYPE OF TEST Agar Cup	13. TEST ORGANISM(S) E. coli Staph. aureus Pseudomonas fluorescens	14. METHOD NO. 4.201	TSD
		15. DURATION 24 hrs.	
		16. CONCENTRATION --	
		17. DILUENT --	

18. SUMMARY

Sample was found to possess bacteriostatic activity against Escherichia coli, Staph aureus and Pseudomonas fluorescens.

19. RESULTS

Zones of inhibition against:

Escherichia coli	1 mm
Staphylococcus aureus	1 mm
Pseudomonas fluorescens	1 mm

20. TESTER'S INITIALS.	21. SIGNATURE OF LAB SUPERVISOR	22. LABORATORY	23. DATE
------------------------	---------------------------------	----------------	----------

SAMPLE SUMMARY ANALYTICAL REPORT	DATE RECEIVED 4/21/76	REGISTRATION NO. 35900-2	SAMPLE NO. 112876
	PRODUCT Hygene Bacteriostatic Water Filter Media		
SEALED Seal broken by Dallas Wright, Jr.			
IDENTIFIED "SN 112876 03-23-76 ALDP Sub 1"			
RECEIVED FROM Dallas Wright, Jr. by hand	CONDITION OF SEALS Broken		LABELING SUBMITTED
DESCRIPTION OF SAMPLE Plastic bag containing broken seal and one 7 oz. plastic bottle with label. Code "Lot No. 03226 B"			
APPEARANCE Black granular solid; no odor			
ANALYSIS	AMOUNT CLAIMED	SATISFACTORY	UNSATISFACTORY
<p>Method: Silver extracted from sample with 1+1 Nitric Acid by shaking 3 hours and standing over weekend. Excess sodium chloride solution added to an aliquot of sample extract; excess titrated with silver nitrate potentiometrically. Silver in sample calculated as metallic silver.</p> <p>Results: 1 - 2.06% 2 - 1.72% 3 - 1.91%</p> <p style="text-align: center;">average - 1.90% silver (as metallic) Claim 1.05% metallic silver</p>			
SIGNATURE OF ANALYST Jack B. Looker <i>[Signature]</i>			DATE REPORTED 4/27/76
RESERVE SAMPLE As rec'd SEALED less 30-35 grams			
SIGNATURE OF SUPERVISOR C. H. Hall <i>[Signature]</i>			DATE 4-27-76

REGISTRATION DIVISION

IONICS, INCORPORATED
Attn: Walter Polens
P.O. BOX 99
Bridgeville, PA 15017

APR 28 1976

Gentlemen:

Subject : HYGENE
EPA Reg. No. 35900-2
Your letters of February 18, 19, 1976 and
March 4, 1976

The general chemistry data is acceptable with the exception of A.5 and B.4. You should submit details of the atomic absorption and the Volhard Methods of Analysis.

In regards to your suggested procedure for evaluation of Hygene Model HY-2 cartridge type filter for EPA Registration. Data derived in accordance with the test protocol submitted would meet the bacteriostatic efficacy data requirements indicated in our letter of December 24, 1975 for a unit which processed municipally treated tap water at a flow rate of 3 gpm for a 18,750-gallon volume capacity. The acceptance of the unit for the efficacy claimed is contingent upon the subsequent evaluation of the data developed in concurrence with labeling claims.

A copy of our recently prepared document "Interim Requirements For Registering Bacteriostatic Water Treatment Units for Home Use" is enclosed to inform you of the test protocol to be used in testing future water treatment units that you develop. At this interim interval, you have the option of developing data by either the test protocol that you submitted or by the one indicated in the document enclosed.

Your submission of December 5, 1975, in reference to Pool Gene, File Symbol 35900-R, is still under review. Due to the nature of the points raised and/or objections stated in your letter in reference to our previous evaluation of your application, it was deemed necessary that each of the five scientific disciplines concerned render their scientific

judgement. Three such evaluations have been made. However, two more are still required. As soon as we have received a response from all of the disciplines involved, the information will be transmitted to you. We expect this review to be completed in approximately two weeks.

Sincerely,

James H. Banks *[Signature]*
Product Manager 33
Disinfectants Branch (WH-567)

Enclosure

WH-567:DIS:RGD:md:59040:Rm 321 4/23/76



IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5108973299

February 18, 1976

Mr. James H. Banks, Product Manager 33
United States Environmental Protection Agency
Disinfectants Branch (WH-567)
Registration Division
401 M Street S. W.
Washington, D. C. 20640

Ref: Your Letter of December 24, 1975 in answer to my Letter of December 3, 1975

Dear Mr. Banks:

I have enclosed with this letter a suggested Procedure for Evaluation
Of HYgene Model HY-2 Cartridge Type Filter for EPA Registration. *sent to TSD*

9-9-77

The reason I am sending this testing procedure along to you before we
spend the money to complete this testing is that the last time we had our HYgene
material tested, we obtained results that Mr. Brown said would get us a self-
sanitizing rating and then after we sent the EPA the results, we were not given a
self-sanitizing rating but a bacteriostatic rating.

Our company is a relatively small company and we can not afford to
waste money. We ask that you please review this as soon as possible and let me
know if we complete this testing, would it suffice to get us a bacteriostatic
rating.

I am aware that the labeling would have to be in line with the label
we have on our bacteriostatic HYgene material.

We ask that you have this reviewed and contact us as soon as possible.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Walter J. Polens
Vice President

WJP:mle

Enclosure

cc: J. D. Collins

92483

84843 189



IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

March 4, 1976

Mr. James H. Banks, Product Manager (33)
United States Environmental Protection Agency
Disinfectants Branch (WH-567)
Registration Division
401 M Street S.W.
Washington, D. C. 20540

Dear Mr. Banks:

Please refer to my letter of December 5, 1975 in reference to
Pool Gene File Symbol 35900-R.

I have not had a reply to this inquiry.

I also call your attention to my letter of February 18, 1976
directed to your attention in reference to a proposed evaluation of our
HYgene Model HY-2 cartridge type filter. I have had no answer to this letter
either.

Your replies to both of these will be very much appreciated.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle

92.27.2

84.843



IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

February 26, 1976

Comp 35900

Mr. James H. Banks, Product Manager (33)
Disinfectants Branch, Room 321
Registration Division (WH-567)
United States Environmental Protection Agency
401 M Street S.W.
Washington, D. C. 20460

Dear Mr. Banks:

Enclosed you will find a copy of the Application for Supplemental Registration of Distributor that was sent to our company. This was marked "Disapproved" because it did not have the signature of an officer from Ionics, Incorporated.

I have signed this form and returned it. I don't know if this is satisfactory or if you need a complete new application.

If a new application is needed, will you please send one along and we will have it executed.

Your prompt attention to the above will be very much appreciated.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Walter J. Polens
Vice President

WJP:mle

Enclosure

cc: Clean Water for America

✓ NOTE: An official of the CLEAN WATER FOR AMERICA MUST SUBMIT A LETTER REQUESTING A DISTRIBUTOR CO. NUMBER. ENCLOSE THIS LETTER WITH YOUR COMPLETED EPA FORM 8570-5.

H. Toma MAR 15 1976

9 2 3 4 5

6 7 8 9 10

REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.
<input type="checkbox"/> INCOMING CALL	<input type="checkbox"/> VISITOR	DATE MAR 15 1976	
<input checked="" type="checkbox"/> OUTGOING CALL	<input type="checkbox"/> CONGRESSIONAL	TIME OF CALL 1000	
NAME AND ADDRESS OF CALLER OR VISITOR Ionics, Inc PO BOX 99 Bridgeville, PA 15017		PHONE NO. (Include Area Code or IDS No.)	
		REGISTRATION, ID NO. OR FILE SYMBOL 35900-2 / PM-33	
		DATE OF LATEST SUBMISSION 4/2 2-26-76	
BRIEF SUMMARY OF CONVERSATION Problem with your 8570-5 and letter of 2-26-76			
ACTION TAKEN OR RECOMMENDED ① Need your EPA Reg. No. on 8570-5 ② Need your signature as official/registrant ③ Will send you instructions and form 8570-5 to be completed and submit to RD/PCB			
RECORDED BY (Name) J. Toma		REFERRED TO (Name)	

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS (771-567)
WASHINGTON, D.C. 20460

APPLICATION FOR SUPPLEMENTAL REGISTRATION OF DISTRIBUTOR

(Please read Instructions on back before completing)

H

NAME AND ADDRESS OF BASIC REGISTRANT (Include Zip Code)

IONICS INCORPORATED
P.O. BOX 99
Bridgeville, PA. 15017

☐ CHECK IF THIS IS A NEW ADDRESS

NAME OF REGISTERED PRODUCT

HYGIENE

PROPOSED DISTRIBUTOR PRODUCT NAME

NAUTILIS

NAME AND ADDRESS OF PROPOSED DISTRIBUTOR (Include Zip Code)

CLEAN WATER FOR AMERICA
315 W. 47th St.
Miami Beach, FLA. 33140

☐ CHECK IF THIS IS A NEW ADDRESS

DISTRIBUTOR

It is requested that we be permitted to market under the Distributor Product Name and Number specified above.

SIGNATURE AND TITLE OF DISTRIBUTOR

Nadine Blevitt
Dept. Treasurer

DATE

12/23/75

REGISTRANT

It is requested that the Registration Record of the basic product specified above be amended to include the Distributor Product specified above.

SIGNATURE AND TITLE OF REGISTRANT

IONICS, inc see enclosed letter

DATE

Oct. 17-75

U.S. EPA

APPROVED - Subject to the conditions specified on the reverse.

☒ DISAPPROVED (See reverse for explanation)

SIGNATURE OF EPA OFFICIAL

DATE

NUMBER
REGISTRATION DISTRIBUTOR

FOR EPA USE ONLY
(Data Systems Evaluation)

FILE SEQUENCE CODE

PRODUCT NUMBER

DATE ACCEPTED

YEAR MONTH DAY

DISTRIBUTOR PRODUCT NAME

EVALUATION CHECKLIST

☐ REGISTRATION NUMBER CONFIRMED

☐ DISTRIBUTOR NUMBER CONFIRMED

☐ REGISTRANT ADDRESS CONFIRMED

☐ DISTRIBUTOR ADDRESS CONFIRMED

☐ BASIC PRODUCT NAME CONFIRMED

☐ PROPOSED DISTRIBUTOR PRODUCT NAME ACCEPTANCE

RECEIVED BY EPA-REGISTRATION DIVISION ON THE DATE STAMPED BELOW



IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

February 19, 1976

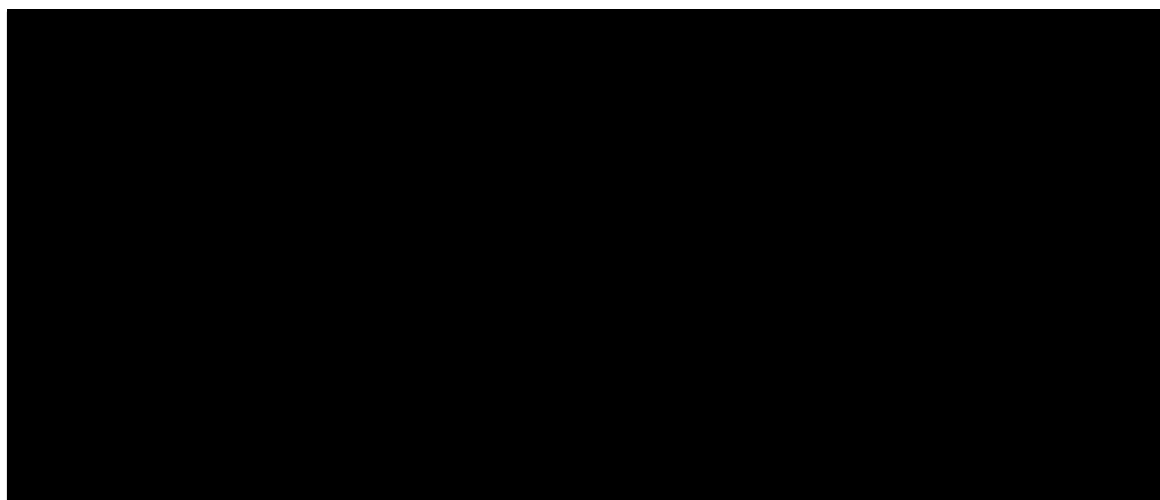
Mr. James H. Banks, Product Manager (33)
Disinfectants Branch
Registration Division (WH-567)
United States Environmental Protection Agency
401 M Street S.W.
Washington, D. C. 20460

Subject: HYgene
EPA Reg. No. 35900-2
Your Letter of Jan. 20, 1976

Dear Mr. Banks:

This is in reply to your letter dated January 20, 1976 in reference to general chemistry data for HYgene.

- A.1 You are correct in stating that the active ingredient is essentially 100% metallic silver with only traces of impurities. OK
- A.2 Correct. Manufacturing process is the same as in Petition 5H5079. OK
- A.3 Purity of ingredients used in the manufacturing process of HYgene are as follows: OK



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88843

- Mr. James H. Banks, Product Manager (33)
Disinfectants Branch
Registration Division (WH-567)
United States Environmental Protection Agency

February 19, 1976
Page 2

A.4 The active ingredient (silver) has been described only
by the word "metallic". These other adjectives would
also be applicable.

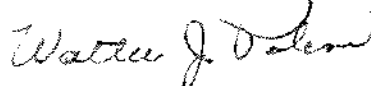
A.5 I do not understand if you are saying you are going to
& send us the information on the testing or if you are

B.4 waiting for us to supply you this information.

I trust this is the information you desire.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant



Walter J. Polens
Vice President

WJP:mle

cc: J. D. Collins - Ionics

92423

84443

SUBMISSION REVIEW RECORD			1. REGISTRATION NUMBER		CYCLE	2. DATE RECEIVED					
3. 3CID PUBLICATION NECESSARY			4. PETITION NO.				5. RECEIVED PM TEAM				
6. METHOD OF SUPPORT			7. PRODUCT MANAGER				NO.	8. PROJECTED RETURN			
9. DATE PULLED			10. DATE PUBLISHED				11. ACTION TYPE		12. OUTGOING DATE		
13. REVIEW TYPE			REVIEWER CODE		SIGNATURE OF REVIEWER		COM- MENT CODE	DATE REVIEW COMPLETED			
14. REVIEW TYPE			REVIEWER CODE		SIGNATURE OF REVIEWER		COM- MENT CODE	DATE REVIEW COMPLETED			
<input checked="" type="checkbox"/>	A	REVIEWABILITY TEAM									
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW									
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW									
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW									
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW	DMD				RL	0	4	1	3
	F	PRODUCT MANAGER									
	G	INTERAGENCY REFERRAL									
	H	COST-BENEFIT REVIEW									
	I	PUBLIC COMMENTS REVIEW									
	J	EEE BRANCH INSECTICIDE EFFICACY									
	K	EEE BRANCH HERBICIDE EFFICACY									
	L	EEE BRANCH FUNGICIDE EFFICACY									
	M	EEE BRANCH RODENTICIDE EFFICACY									
<input checked="" type="checkbox"/>	N	EEE BRANCH DISINFECTANT EFFICACY	DmP					0	3	3	1
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY									
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY									
	Q	TOXICOLOGY BRANCH HUMAN SAFETY									
	R	EEE BRANCH ENVIRONMENTAL SAFETY									
	S										
	T										
PRODUCT MANAGER SIGNATURE			TYPE OF RESPONSE						CODE		

EEE BRANCH REVIEW

DATE: IN _____ OUT _____ IN _____ OUT _____ IN 3/31 OUT 3/31/76
FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 35900-2

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 2-24-76

DATE OF SUBMISSION 2-18-76

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): I, (b), H, F, N, R, S Bacteriostatic Water Filter

PRODUCT MGR. NO. 33

PRODUCT NAME(S) Hygene Model HY-2 Cartridge Type Filter

COMPANY NAME Ionics, Inc.

SUBMISSION PURPOSE Resubmission without data

CHEMICAL & FORMULATION _____

- 200.0 Introduction
- 200.1 Use: Bacteriostatic Water Filter
- 200.2 Background information: This submission includes a test protocol in response to efficacy data requirements indicated in our letter of December 24, 1975.
- 202.0 Recommendations
- 202.1 Claims supported by data derived by proposed test protocol: Data derived in accordance with the test protocol submitted would meet the bacteriostatic efficacy data requirements indicated in our letter of December 24, 1975 for a unit which processed municipally treated tap water at a flow rate of 3 gpm for a 18,750-gallon volume capacity. The acceptance of the unit for the efficacy claimed is contingent upon the subsequent evaluation of the data developed in concurrence with labeling claims.

A copy of our recently prepared document "Interim Requirements For Registering Bacteriostatic Water Treatment Units for Home Use" is enclosed to inform you of the test protocol to be used in testing future water treatment units that you develop. At this interim interval, you have the option of developing data by either the test protocol that you submitted or by the one indicated in the document enclosed.

Dorothy M Portner *W3W*
Dorothy M. Portner 3/31/76 *JH*
Efficacy Section
Efficacy and Ecological Effects Branch

REVIEW COMMENTS SHEET	1. Application Date	2. Registration N 35900-2
3. Response Code	4. Date Received	5. Telephone No. 59042
6. Applicant Name & Address	7. Originator James H. Banks Pm-33 Disinfectants Branch WH-567	
8. Product Name		

COMMENTS

A5-B4 We are saying that you
are soon going to submit details of
the AA and Vothard methods.

RL JH 3-30-76

2-A _____ 2-B _____ 2-C _____ Review under revised Sec. 3 Reg. Yes _____ No _____

Date of Submission: 5-11-76 Reg/EXP 35900-2 Petition No. _____

Product Name _____
Company Tonics, Inc.

Type of Product: I R H F D

Product Manager (name): Barks

Type Submission-
Rm# 321

Petition
New Product -New Chem. _____
New Product Old Chem _____
Amended Reg. Substantive _____
Amended Reg. Nonsubstantive _____

Reviews Needed	Rec'd by E. Gross	Sent to Reviewer	Date Completed	Returned to PM
RET			<u>5-26-76</u>	<u>5-26-76</u>

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling

Letter Additional gen. chem. data submitted notes

FEER

EFFICACY

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling

Letter

FSM

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling

Letter

ENV. CHEM.

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling

Letter

TOX SR.

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling

Letter

CHEM BR.

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

February 19, 1976

Mr. James H. Banks, Product Manager (33)
Disinfectants Branch, Room 321
Registration Division (WH-567)
United States Environmental Protection Agency
401 M Street S.W.
Washington, D. C. 20460

Dear Mr. Banks:

Subject: HYgene
EPA Reg. No. 35900-2
Your Letter of Dec. 4, 1975

We have tried to analyze your letter of December 4, 1975 and since you say our letter of November 13, 1975 does not answer the questions you desire, I assume you are asking questions about the finished product of [REDACTED] on their which was registered with you under Reg. No. 35900-2. I, therefore, assume this is why you were not satisfied with our answers in our letter of November 13, 1975. If this is the case, you would have to get additional information from [REDACTED] because we do not know what else they do with the product or add to the product after we ship to them.

If I can be of any further service, please contact me.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle

cc: J. D. Collins

92433
92443

JAN 2

Ionics, Incorporated
Attn: Walter Polans
P.O. Box 99
Bridgeville, PA 15017

Dear Sir:

Subject: Hygene
EPA Reg. No. 35900-2

We will accept your general chemistry data for HYGENE media and all products using your media if you verify that the following information is correct:

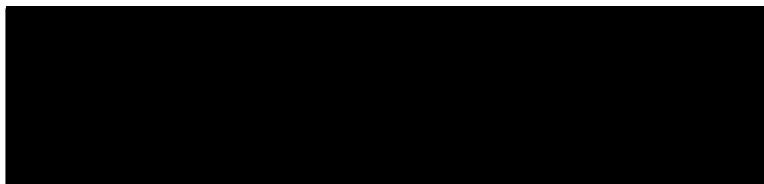
A.1 Complete composition of technical chemical used as active ingredient:

Essentially 100% metallic silver formed in situ,
with only traces of impurities.

A.2 Manufacturing process of the technical chemical:

Same as in Petition 5H5079

A.3 Purity of starting and intermediate materials used in the manufacturing process:



A.4 Basic physical and chemical characteristics of the active ingredient(s):

Malleable, ductile, metallic, heavy, sensitive to light

Page 2

A.5 Details of the atomic absorption and the Volhard methods of analysis
& will be submitted soon.
B.4

Your immediate response to this letter is requested.

Sincerely,

James H. Banks *JHB*
Product Manager (33)
Disinfectants Branch
Registration Division (WH-567)

WH-567::DB:JHBANKS:bab:rm 219WSME, x68815:1/16/76

REGISTRATION DIVISION

IONICS, INCORPORATED
Attn: Walter J. Polens
P.O. Box 99
Bridgeville, PA 15017

Gentlemen:

Subject : HYGENE
EPA Reg. No. 35900-2
Your letter of December 3, 1975

This is in response to your letter of December 3, 1975 in reference to your proposed product named HY2 Water Cleaner.


Although we do expect good engineering principles to be applied to water treatment products utilizing silver filtering media, interpolation and/or extrapolation of data developed to demonstrate efficacy of the filtering media per se is not acceptable to substantiate efficacy of a specific water treatment product.

Silver release data for 10 product units and bacteriological data for 3 product units and 3 corresponding activated carbon controls must be provided to substantiate efficacy of the product identified as "HY2 Water Cleaner" when manufactured with silver filtering media.

Data developed over the lifetime of the product must be provided to support claims for the removal of pesticides, phenols, and detergents.

The earlier information provided that separate EPA Registration Numbers will be required for each individual water treatment product, including replacement filters still applies. The registration number issued (EPA Reg. No. 35900-2) only covers the production and sale of the HYGENE medium and should not be misconstrued as pertaining to any individually manufactured water treatment unit.

Sincerely,

James H. Banks 
Product Manager 33
Disinfectants Branch (WH-567)

WH-567:DIS:EGD:md:59040:12-23-75:Bm 321



IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

December 3, 1975

35900-2

Mr. James H. Banks
United States Environmental Protection Agency
Disinfectants Branch, Room 321
Registration Division (WH 567)
OPP-EPA
401 M Street S. W.
Washington, D. C. 20640

Dear Mr. Banks:

Enclosed with this letter please find a specification sheet on our General Ionics HY2 Water Cleaner.

I wanted to discuss the registration of this cleaner with you during my visit to your office on November 19. Since you were tied up in a meeting that day and I was unable to discuss this in person, I thought I would send it to you in this letter.

Ionics, Inc. is at present producing small HY2 Water Cleaners with plain Activated Carbon. Ionics, Inc. respectfully requests the EPA to grant Ionics, Inc. the usage of its EPA registration number 35900-2 on this HY2 Water Cleaner. We propose to replace the plain Activated Carbon in this filter with our HYgene bacteriostatic water filtering media registered with you under 35900-2. Ionics, Inc. proposes to operate this HY2 Water Cleaner within all of the test flow rates that it supplied to EPA with its request for registration of its HYgene media.

Ionics, Inc. contends that since it performed the tests to show that its product HYgene is an effective bacteriostatic product, if we scale up or down - as long as we stay within good engineering principles - EPA should allow the one EPA number to apply to all different sizes of the same product. Ionics, Inc. agrees that if any changes are made to the media or any drastic changes made in design or flow, then this would be a different product and would require a separate registration.

15-00-52

15-00-52

Mr. James H. Banks
United States Environmental Protection Agency

December 3, 1975
Page 2

Ionics, Inc. respectfully requests your prompt attention to the above.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant



Walter J. Polens
Vice President

WJP:mle

Enclosure

cc: Mr. Elijah Brown

75-0-12

ENH-10

GENERAL IONICS HY2 WATER CLEANER



(Size: 5 3/8" Dia. x 13 1/2" Height)

The GENERAL IONICS Hy-2 WATER CLEANER is an Activated Carbon filter. It is designed for efficient removal of organic impurities found in potable water supplies. These impurities include tastes, odors, color, insecticides, pesticides, herbicides, detergents, phenols and other contaminants from both natural and industrial sources. The Hy-2 Water Cleaner will also remove turbidity and suspended solids found in water to levels comparable with sand filtration.

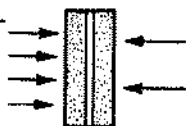
In addition to the absorption and filtration function of the Hy-2 Water Cleaner, it is also capable of concurrently removing excess oxidants such as chlorine used in pretreatment application by municipal water supplies.

Hy-2 WARRANTY: The obligation of GENERAL IONICS, INC., under this warranty shall be limited to the repair or exchange of any part or parts which may thus prove defective under normal use and service within one year from the date of purchase.

TURN ON

TASTE, ODOR AND DIRT REMOVAL

1. Full flow with bonded activated carbon element



TURN OFF

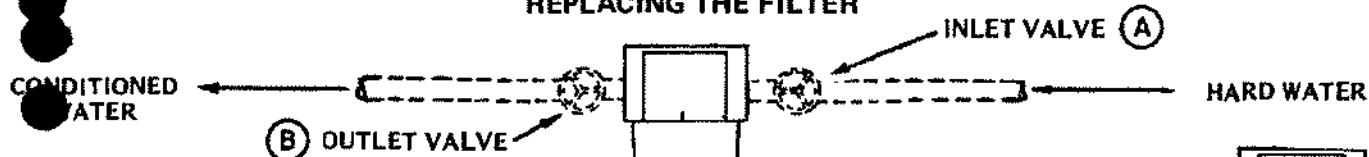
Naturally occurring tastes, odor and sediment



Taste, odor and dirt in drinking and cooking water.



REPLACING THE FILTER

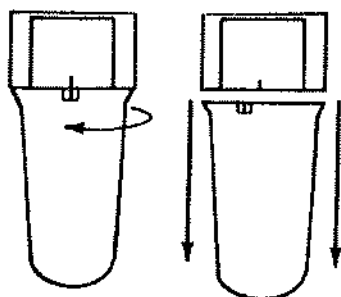


1. Close Valve 'A'.
2. Close Valve 'B'.

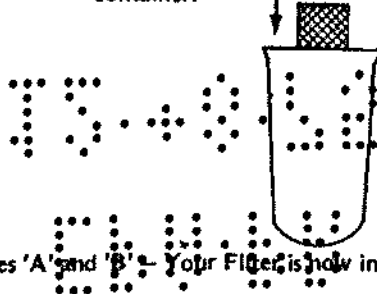
3. Depress red vent button until pressure is relieved.



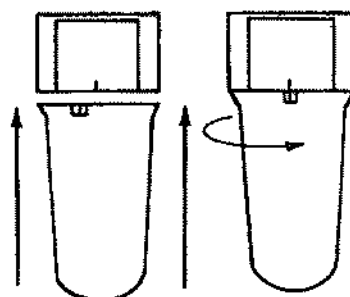
4. Turn the filter element container left an eighth turn to stop and lower carefully.



5. Unwrap the filter element according to the directions on the label and place it in the container.



6. Replace container and turn right to stop with index marks in line.



7. Open Valves 'A' and 'B'. Your Filter is now in operation.



IONICS
IONICS (INCORPORATED)

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

December 3, 1975

United States Environmental Protection Agency
Disinfectants Branch, Room 311
Registration Division (740-1-7)
OPP-EPA
401 M Street S. W.
Washington, D. C. 20640

Attention: Mr. James Banks

Dear Mr. Banks:


This letter will authorize you to use information in our file under our EPA Registration No. 35900-2 for the evaluation of a water filter manufactured by [REDACTED]

This letter gives you authorization to refer to our file but not to make available to [REDACTED] any confidential material in the file.

If you have any questions concerning this, please contact me.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant


Walter J. Polens
Vice President

WJP:mle

cc: [REDACTED]



REGISTRATION DIVISION

IONICS, INCORPORATED
Attn: Walter J. Polens
P.O. Box 99
Bridgeville, PA 15017

Gentlemen:

Subject : HYGENE
EPA Reg. No. 35900-2
Your letter of November 13, 1975

The general chemistry information submitted with the referenced letter in support of [REDACTED] is not acceptable.

1. Apparently you did not quite understand our request. The general chemistry requirements are in two (2) parts. The first part, (A), refers to the technical chemical used as the active ingredient (in this case-- elemental silver) and the second part, (B), refers to the specific pesticide formulation (in this case-- a water filter containing silver and carbon). The information required is as follows:

- A. Information on the technical chemicals used as the active ingredients in the pesticide, including:
 1. Complete composition of the technical chemical, including the chemical names and percentages of impurities;
 2. Basic manufacturing process of the technical chemical.
 3. Purity of starting and intermediate materials used in the manufacturing process;
 4. Basic physical and chemical characteristics of the active ingredient(s), either in technical or purer form;
 5. Analytical methods for the principal component(s) and impurities.
- B. Information on the specific pesticide formulation including:
 1. Method(s) of analysis for identifying and quantifying the active ingredient(s) in the pesticide formulation.

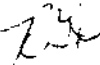
2. Note that "basic physical and chemical characteristics", in A(4) above, mean - structural formula, melting point, boiling point, vapor pressure, density, hydrolysis rate, solubility, dissociation constants, stability, physical state, color and odor. You have not supplied any of this information.

3. Submit more details of the atomic absorption method.

4. We accept your storage stability data as satisfactory.

5. Your attachment A(Method for determining total silver content of Hygene) is not acceptable because it is incomplete. Exactly how do you analyze for silver? You say "Take aliquot for quantitative analyses of silver." However, that is the end of the method. Please explain.

Sincerely,


James H. Banks
Product Manager 33
Disinfectants Branch (WH-567)

WH-567:DIS:RGD:md:59040:12-2-75:Rm 321

Note to File

Letter dated 11-13-75
has been placed in the
"Confidential" envelope.



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

November 12, 1975

United States Environmental Protection Agency
Disinfectants Branch, Room 321
Registration Division (WH-567)
OPP-EPA
401 M Street S.W.
Washington, D. C. 20640

Attention: Mr. James H. Banks - PM 33

Dear Mr. Banks:

This letter will confirm our meeting in your office on November 19 at 10 a.m.

At this meeting I would like to discuss with you and some of your personnel the application of our HYgene in some of our larger units and also, now that we have an approval on HYgene, I think we could now talk to you about the possibility of using this in our Pool Gen® swimming pool unit.

I want to thank you for arranging this meeting and giving us the opportunity of discussing these products with you.

I shall look forward to seeing you at that time.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle

NRN-11-19-75

2077

212

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION
WASHINGTON, D.C. 20460

EPA REGISTRATION NUMBER

DATE OF ISSUANCE

October 21, 1975

NAME OF PESTICIDE PRODUCT

HYGENE

NOTICE OF REGISTRATION

(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT

☒ Ionics, Incorporated
Attention: Mr. Walter J. Polens
P.O. Box 95
Bridgeville, Pennsylvania 15017

OCT 25 1975

NOTE: Changes in labeling or formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of the information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act.

☒ Copy of the labeling accepted in connection with this registration is returned herewith.

Registration is in no way to be construed as an endorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The following paragraphs are applicable only when checked:

☐ The registration for this product is being issued with the understanding that certain defects in the labeling which are noted below will be corrected as soon as possible. Objection is not raised to the use of the present labeling for a reasonable period of time while fully corrected labeling is being prepared. Three copies of the corrected labeling must be submitted.

☒ 1. Revise the first two paragraphs of the letter to be sent to your customers as follows.

"This letter is to inform you that Ionics, Incorporated has a bacteriostatic water filter media product, Hygene, EP-100, \$ 35.00/lb."

"Hygene has been laboratory tested to demonstrate bacteriostatic activity. The filter media will inhibit the growth of bacteria which is entrained during the treatment of water."

2. It has been noted that you are not going to distribute any collateral literature, such as brochures or bulletins, with this product. However, it should be understood that before any such literature is distributed with this product, it must be first accepted by this Agency.

☐ Attachment is applicable.

SIGNATURE OF APPROVING OFFICIAL

DATE

2

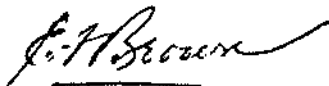
Note that this submission was processed and accepted under current requirements. At such time as re-registration is required or amendments are proposed, the Registration, Re-registration and Classification Procedures, as published in the Federal Register on July 3, 1975, will be applied. Refer to Section 162.23 of that document. Refer also to PR Notice 75-1.

Sincerely,



James H. Banks
Product Manager 33
Disinfectants Branch
Registration Division

Enclosure



Stamped Label

WH-567:DIS:RDOUGLAS:ca:10/29/75:559041:rm-321

cc: PED



ACCEPTED

OCT 29 1975

BACTERIOSTATIC WATER FILTER MEDIA

Inhibits the growth of bacteria

GENERAL INSECTICIDE
FUNGICIDE AND ROENTGENIDE ACT.
FOR ECONOMIC PERSON PROTECTION
EPA REG. NO. 35900-2

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and chemical fumes.

EPA Reg. No. 35900-2

EPA Est. No. 35900 PA 01

ACTIVE INGREDIENT

METALLIC SILVER ----- 1.05% LOT NO. _____

INERT INGREDIENT

ACTIVATED CARBON ----- 98.95%

DIRECTIONS FOR USE: -----

NET CONTENTS _____ cu. ft.

Flow rate is not to exceed 15 GPM per cu. ft. of media. Bed depth must be at least twice the diameter.

DISPOSAL OF SPENT MEDIA: -----

Retain shipping carton and plastic liner for disposing of exhausted filter media with trash.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment-

IONICS, INCORPORATED

Routes 519 & 50, Bridgeville, Penna. 15017

SUBMISSION REVIEW RECORD				1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED		
3. 3CID PUBLICATION NECESSARY				4. PETITION NO.					MO	DAY	YR
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO											
6. METHOD OF SUPPORT				7. PRODUCT MANAGER				NO.	8. PROJECTED RETURN		
<input type="checkbox"/> 2A <input type="checkbox"/> 2B <input type="checkbox"/> 2C				Banks				33	MO	DAY	YR
9. DATE PULLED		10. DATE PUBLISHED		11. ACTION TYPE				CODE	12. OUTGOING DATE		
				Resubmission without data				51	MO	DAY	YR
REV. SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER				COM-MENT CODE	DATE REVIEW COMPLETED		
									MO	DAY	YR
	A	REVIEWABILITY TEAM									
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW									
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW									
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW									
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW		BGD R. Douglas					12	22	75
	F	PRODUCT MANAGER									
	G	INTERAGENCY REFERRAL									
	H	COST-BENEFIT REVIEW									
	I	PUBLIC COMMENTS REVIEW									
	J	EEE BRANCH INSECTICIDE EFFICACY									
	K	EEE BRANCH HERBICIDE EFFICACY									
	L	EEE BRANCH FUNGICIDE EFFICACY									
	M	EEE BRANCH RODENTICIDE EFFICACY									
	N	EEE BRANCH DISINFECTANT EFFICACY		DMP D. Partner							
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY									
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY									
	Q	TOXICOLOGY BRANCH HUMAN SAFETY									
	R	EEE BRANCH ENVIRONMENTAL SAFETY									
	S										
	T										
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE				CODE			
James S. Banks				Reg. Tr.							



IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A.C. 412 343-1040 TWX 5106973299

October 14, 1975

AIRMAIL - SPECIAL DELIVERY - CERTIFIED MAIL - RETURN RECEIPT REQUESTED - ADDRESS ONLY

United States Environmental Protection Agency
Disinfectants Branch, Room 321
Registration Division (WH-567)
OPP - EPA
401 M. Street, S.W.
Washington, D.C. 20640

Attention: Mr. James H. Banks - PM 33

Subject: HYGENE
Ionics File Symbol 35900-E
Your letter dated October 9, 1975

Dear Mr. Banks:

Five finished labels for the above HYgene product are enclosed. On this label, we have made the following changes as requested in your letter dated October 9, 1975:

- 1) We have changed "Self-sanitizing" to read "Bacteriostatic".
- 2) We have changed the claim "Prevent the growth of bacteria" to read "Inhibits the growth of bacteria".
- 3) We have deleted "as a sanitizer".
- 4) We have corrected the typographical error in the spelling of silver.
- 5) In your letter under paragraph 5, you ask us to provide the necessary calculations to verify the flow rate recommended on the label is comparable to the flow rate used in these laboratory experimentation studies.

You may use the following equations to convert the 500 ml/minute and this will show that this is the same as 15 gallons per minute. The equation is as follows:

500 ml flow through column of 250 cc HYgene mineral is directly proportional to 15 gallons per minute per cubic foot of HYgene as follows:

- a) $500 \text{ ml/min.} = 0.132 \text{ gal./min.}$
- b) $250 \text{ cc HYgene} = 0.008828 \text{ cubic foot}$
- c) $0.132 \text{ gal./min.} / 0.008828 \text{ cubic foot} = 15 \text{ gals. per minute per one cubic foot.}$

- 6) We have no collateral literature or technical bulletins or brochures that are being distributed with this product at present.

We have enclosed a copy of a letter that is being sent to all of our customers. If any literature or collateral material is developed to be sent with the product, we will send this to you for your approval.

In your letter dated October 9, 1975 under paragraph "D" 1, 2, 3, and 4 - you asked for additional information required to substantiate the bacterio-static claim for the filter media.

- 1) Attached please find a letter from Ms. Linda Deans, Manager of Analytical Services for NUS Corporation who did the testing. In this letter Ms. Deans gives the concentration of the artificially contaminated water (inoculum) at the end of the test to ascertain the degree of natural "dieoff".
- 2) The neutralizing solution used contained 5% sodium thioglycollate and 7.3% sodium thiosulfate. One milliliter of this sterile neutralizing solution was added to sterile sample bottles in which 100 milliliters samples were collected for bacteriological testing.
- 3) Attached is a copy of our report "EVALUATION OF HYGENE PRODUCT MEDIA FOR EPA REGISTRATION". This was originally sent to you on September 3, 1975. Please note on page one under CHEMICAL, there is a listing of the production lots used for testing. Three of these lots are as follows:

Lot No. 05125, Lot No. 04075, Lot No. 03105

On page three of this report under BACTERIOLOGICAL, we list the three lot numbers used for bacteriological testing.

Lot No. 05125, Lot No. 04075, Lot No. 03105

Please note that these are both from the same lot numbers that we used in the chemical testing.

I refer you to the last paragraph on page two which states "Flow was discontinued to all three columns for a period of eighteen (18) hours." These samples were then acidified and sent to NUS Corporation with the suffix "C" and tested by atomic absorption for silver concentration. This included lot numbers 05125, 04075, and 03105. They were identified then as lot numbers 05125C, 04075C, 03105C. Attached to the above reference report is the NUS Corporation Atomic Absorption Test Report on the silver by lot numbers. None of the three lots went over the 50 ppb after an eighteen hour holding period. This conclusively proves that from these lots even sitting eighteen hours, we did not exceed 50 ppb. These are the lots that we used for the bacteriological tests.

United States Environmental Protection Agency

October 14, 1975

Attention: Mr. James H. Banks - PM 33

Page 3

- 4) Attached is the letter from Ms. Linda Deans Manager of Analytical Service for NUS Corporation that I referred to under "D" - 1. In this letter she mentioned that she used Standard Methods membrane filter technique for the bacteriological assay.

As requested in your letter, in order to expedite the handling of this data, we have returned the duplicate copy of your letter. We respectfully request your immediate evaluation so that we can supply some of our customers who have already been issued there EPA registration number.

Yours very truly,

IONICS, INCORPORATED
Bridgeville Plant


Walter J. Polens
Vice President

WJP/mp

cc: Mr. E. F. Brown, Chief

Encls: ..

- 1) Five (5) labels
2) Customer Notification of EPA letter
3) Copy of EPA letter dated October 9, 1975
4) NUS letter from MS, Linda Deans
5) EVALUATION OF HYGENE PRODUCT MEDIA FOR EPA REGISTRATION"

Quality control process information may be entitled to confidential treatment



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

Water Conditioning Equipment • Custom Fabrication for the Nuclear, Chemical & Food Industries • Heat Transfer Equipment

NOTE TO EPA: This letter will be sent to our accounts after we have received official notification of having been granted our EPA registration number.

This letter is to inform you that Ionics, Incorporated has been granted its Federal Registration Number from the Environmental Protection Agency for its product HYgene.

HYgene has been registered under the Federal Insecticide/Fungicide/Rodenticide Act and has received a Bacteriostatic rating. The Federal Government allows us to make the following claim - that our product will inhibit the growth of bacteria.

We can now honor all purchase orders and make immediate shipment of this product.

We are enclosing our current O.E.M. price list.

May we look forward to hearing from you with your requirements.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle

Enclosure

92.7.07
84.8.13

Quality control process information may be entitled to confidential treatment

REGISTRATION DIVISION

IONICS, INC.
Attn: Walter J. Polens
P.O. Box 99
Bridgeville, PA 15017

OCT 09 1975

Gentlemen:

Subject : HYGENE
File Symbol 35900-E
Your submission of September 3, 1975

The product referred to above will be acceptable for registration under the Federal Insecticide, Fungicide, and Rodenticide Act; provided, finished labeling is submitted incorporating the following revisions.

1. Change "Self-sanitizing" to read "bacteriostatic". ✓
2. Change the claim "Prevent the growth of bacteria" to read "Inhibits ✓
the growth of bacteria."
3. Delete "as a sanitizer." ✓
4. Note the correct spelling of silver.
5. Provide the necessary calculations to verify that the flow rate recommended on the label is comparable to the flow rate used in these laboratory experimentation studies.
6. Any collateral literature, such as technical bulletins or brochures, distributed in conjunction with this product must be submitted for review. ?

Based on an evaluation of the data submitted, the following conclusions were made:

- A. Claims supported by data: The requirement to demonstrate that the silver concentration of the effluent water does not exceed 50 ppb after treatment is fulfilled by the chemical data provided.
- B. Data not appropriate: The bacteriological data are inappropriate to support a self-sanitizing claim for filter media. To support such a claim, a study must be designed to demonstrate (1) that the filter media does retain bacteria in sufficient number and (2) that the filter media does effectively and significantly reduce the bacterial population retained.

- C. Lesser claim the data will support: The data provided suggest inhibition of bacterial growth in water stagnated within the filter media for 10 hours.
- D. Additional information required: To substantiate the bacteriostatic claim for the filter media, the following additional information must be provided:
- 1) The concentration of the artificially contaminated water (inoculum) at the end of the test is required to ascertain the degree of natural "dieoff".
 - 2) The neutralizer used must be identified.
 - 3) Determinations of the silver content in the effluent from the three test units used to derive the bacteriological data are required.
 - 4) Bacteriological assay method used to derive counts on the effluent from the control and test units must be submitted.

TEPA Reg. No. 35900-2" is being reserved for this product. This must appear on the finished label. The "Notice of Registration" will be issued when five (5) copies of the acceptable finished (printed) labeling are submitted. Finished labeling is that which will be attached to or accompany the product. Refer to the attached A-79 Enclosure.

To expedite handling, please return the enclosed duplicate copy of this letter with your finished labeling.

This letter does not constitute registration, and the product may not be lawfully marketed in interstate commerce until it is registered.

Sincerely,



James H. Banks
Product Manager 33
Disinfectants Branch (WH-567)

Enclosure

A-79 Encl.
Duplicate letter

WH-567:DIS:RGD:md:59040:10-9-75:Rm 321



IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5108973299

October 8, 1975

CERTIFIED MAIL - RETURN RECEIPT REQUESTED
DELIVER TO ADDRESSEE ONLY

Mr. E. F. Brown
Chief, Disinfectants Branch
Registration Division (WH-567)
United States Environmental Protection Agency
401 M Street S.W.
Washington, D. C. 20460

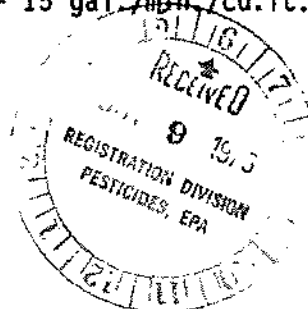
SUBJECT: HYGENE - Ionics File Symbol 35900-E
Ionics EPA Registration No. 35900-2

Dear Mr. Brown:

This letter will confirm our telephone conversation of Friday, October 3, 1975. From this phone conversation it is my understanding that the United States Environmental Protection Agency will issue to Ionics, Incorporated on their product HYgene EPA Registration No. 35900-2. This number will be issued as soon as you receive the enclosed (5) labels that have the following revisions from the original label sent to Mr. James H. Banks on September 3, 1975.

The revisions on the labels are as follows:

1. We have changed the word "Self-sanitizing" to "Bacteriostatic".
2. We have changed the claim "Prevents the growth of bacteria" to "Inhibits the growth of bacteria".
3. We have deleted "As a sanitizer".
4. We are providing the following necessary calculations to verify that the flow rate of 15 gpm/cu.ft. recommended on the label is comparable to the flow rate used in our laboratory experimentation studies. In these studies we used 500 ml./min. flow through a column of 250 cc of HYgene mineral. This is directly proportional to 15 gpm/cu.ft. of HYgene as follows:
 - a. $500 \text{ ml./min.} = 0.132 \text{ gpm}$
 - b. $250 \text{ cc HYgene} = 0.008828 \text{ cu.ft.}$
 - c. $0.132 \text{ gal./min.} / 0.008828 \text{ cu.ft.} = 15 \text{ gal./min./cu.ft.}$
by direct proportion.



*Superseded by
submission of
16-74-75
AGP*

Mr. E. F. Brown
Chief, Disinfectants Branch
Registration Division (WH-567)
United States Environmental Protection Agency

October 8, 1975
Page 2

It is our understanding that we are to provide you with copies of any collateral literature such as technical bulletins and brochures distributed in connection with this product for your review. At the present we have no literature that will be sent with the product. We are enclosing a copy of a letter we are sending to some of our potential customers.

I would like to take this opportunity to thank you and all of your staff for the cooperation we received.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

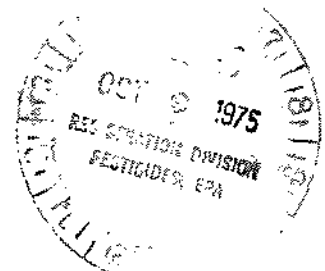


Walter J. Polens
Vice President

WJP:mle

Enclosures

cc: Mr. James H. Banks





P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5108973299

Water Conditioning Equipment • Custom Fabrication for the Nuclear, Chemical & Food Industries • Heat Transfer Equipment

This letter is to inform you that Ionics, Incorporated has been granted its Federal Registration Number from the Environmental Protection Agency for its product HYgene.

HYgene has been registered under the Federal Insecticide/Fungicide/Rodenticide Act and has received a Bacteriostatic rating. The Federal Government allows us to make the following claim - that our product will inhibit the growth of bacteria.

We can now honor all purchase orders and make immediate shipment of this product.

We are enclosing our current O.E.M. price list.

May we look forward to hearing from you with your requirements.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle

Enclosure





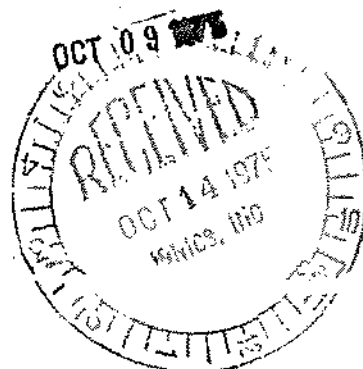
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460
REGISTRATION DIVISION

IONICS, INC.
Attn: Walter J. Polens
P.O. Box 99
Bridgeville, PA 15017.

Gentlemen:

Subject : HYGENE
File Symbol 35900-E
Your submission of September 3, 1975



The product referred to above will be acceptable for registration under the Federal Insecticide, Fungicide, and Rodenticide Act; provided, finished labeling is submitted incorporating the following revisions.

1. Change "Self-sanitizing" to read "bacteriostatic".
2. Change the claim "Prevent the growth of bacteria" to read "Inhibits the growth of bacteria."
3. Delete "as a sanitizer."
4. Note the correct spelling of silver.
5. Provide the necessary calculations to verify that the flow rate recommended on the label is comparable to the flow rate used in these laboratory experimentation studies.
6. Any collateral literature, such as technical bulletins or brochures, distributed in conjunction with this product must be submitted for review.

Based on an evaluation of the data submitted, the following conclusions were made:

- A. Claims supported by data: The requirement to demonstrate that the silver concentration of the effluent water does not exceed 50 ppb after treatment is fulfilled by the chemical data provided.
- B. Data not appropriate: The bacteriological data are inappropriate to support a self-sanitizing claim for filter media. To support such a claim, a study must be designed to demonstrate (1) that the filter media does retain bacteria in sufficient number and (2) that the filter media does effectively and significantly reduce the bacterial population retained.

92-27-07

84-843

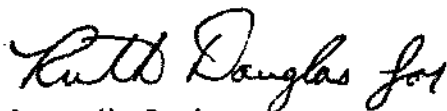
- C. Lesser claim the data will support: The data provided suggest inhibition of bacterial growth in water stagnated within the filter media for 10 hours.
- D. Additional information required: To substantiate the bacteriostatic claim for the filter media, the following additional information must be provided:
- 1) The concentration of the artificially contaminated water (inoculum) at the end of the test is required to ascertain the degree of natural "dieoff".
 - 2) The neutralizer used must be identified.
 - 3) Determinations of the silver content in the effluent from the three test units used to derive the bacteriological data are required.
 - 4) Bacteriological assay method used to derive counts on the effluent from the control and test units must be submitted.

"EPA Reg. No. 35900-2" is being reserved for this product. This must appear on the finished label. The "Notice of Registration" will be issued when five (5) copies of the acceptable finished (printed) labeling are submitted. Finished labeling is that which will be attached to or accompany the product. Refer to the attached A-79 Enclosure.

To expedite handling, please return the enclosed duplicate copy of this letter with your finished labeling.

This letter does not constitute registration, and the product may not be lawfully marketed in interstate commerce until it is registered.

Sincerely,



James H. Banks
Product Manager 33
Disinfectants Branch (WH-567)

Enclosure

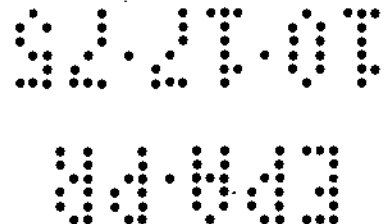
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FINISHED LABELING

Finished labeling is defined as the complete markings and text that appear on or accompany the product. Finished labeling must be legible and the graphic design must not be misleading.

Submitting Procedures.

- I. When screen printing or embossing is used to print labeling directly on the container (cans, bottles, boxes, etc.), do not submit the containers. Such labeling should be submitted after it is reproduced as follows:
 - A. Screen Printing. Request your printer to supply finished copies of the labeling on paper for convenient filing. Copies may be obtained by taping a piece of paper on the container as it goes through the printing process.
 - B. Embossing. Photo copy this labeling.
- II. When paste-on labeling is used, submit the actual labeling.
- III. When the labeling involves large containers such as bags or boxes, submit legible, photo-reduced copies indicating the fraction of the actual size. The actual bags or boxes are not acceptable and will be returned. If the photo-reducing process makes the labeling illegible, any one of the following methods for submitting finished labeling would be acceptable:
 - A. Photo-reduce the labeling to an acceptable size which would fit in a letter-size file folder,
 - B. Photo-reduce the labeling in sections, so that each sheet is approximately 8-1/2 by 11 inches, or
 - C. Photo-reduce the labeling to 8-1/2 by 11 inches, and submit the labeling text in typewritten form.
- IV. When the labeling is smaller than 40 square inches, copies should be attached to a sheet of paper (8-1/2 by 11 inches).





P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

Water Conditioning Equipment • Custom Fabrication for the Nuclear, Chemical & Food Industries • Heat Transfer Equipment

NOTE TO EPA: This letter will be sent to our accounts after we have received official notification of having been granted our EPA registration number.

This letter is to inform you that Ionics, Incorporated has been granted its Federal Registration Number from the Environmental Protection Agency for its product HYgene.

HYgene has been registered under the Federal Insecticide/Fungicide/Rodenticide Act and has received a Bacteriostatic rating. The Federal Government allows us to make the following claim - that our product will inhibit the growth of bacteria.

We can now honor all purchase orders and make immediate shipment of this product.

We are enclosing our current O.E.M. price list.

May we look forward to hearing from you with your requirements.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle

Enclosure

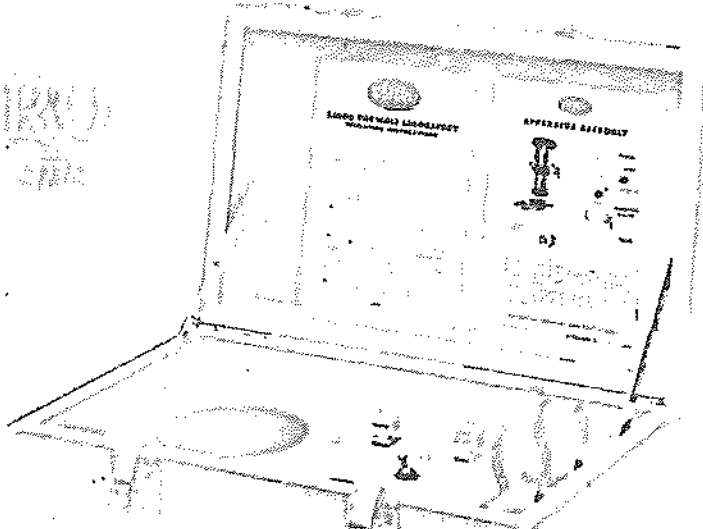
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Figure
#5

SABRO
LABORATORY

PROCEDURE VARIATIONS
FOR BACTERIOLOGICAL
ANALYSIS IN WATER



- Complete, compact portable laboratory
- Built-in incubator permits fast, accurate analysis of up to 18 samples
- Provides low-cost, permanent day-to-day records
- Ready-to-use disposable sterile culture can assemblies for Colliform or Total Count
- Magnetized drawer holds culture cans in place when moved during incubation
- Easy-to-clean stainless steel filtration units with polished interior surface

The portable Sabro Laboratory, using the Membrane Filter Technique, is in daily use throughout the world. It has been given the status of Standard Procedure in the 11th edition of *Standard Methods for the Exami-*

nation of Water, Sewage and Industrial Wastes, published jointly by the American Public Health Association, the American Water Works Association, and the Federation of Sewage and Industrial Wastes Association.



IONICS, INCORPORATED

P.O. Box 99, Bridgeville, Pennsylvania 15017 (Pittsburgh District)
65 Grove Street, Watertown, Massachusetts 02172 (Boston District)

SABRO® PORTABLE LABORATORY

MEMBRANE FILTER TECHNIQUE

FOR BACTERIOLOGICAL EXAMINATION OF WATER

The Sabro Portable Laboratory, employing the Membrane Filter technique, provides accurate and rapid bacteriological analysis of water. The incubator, built into the laboratory, permits incubation of water samples in 18-20 hours and temperature control within ± 1 F. As many as 18 samples can be incubated simultaneously with samples held firmly in place inside the incubator drawer to permit transporting the lab during incubation.

Disposable, sterile culture can assemblies are ready for use, minimizing expense and trouble in preparing equipment. Incubated membranes provide safe and permanent records of the examination when treated with a 10% glycerol solution. The Sabro Laboratory technique permits permanent day-to-day records at very low cost.

The Sabro Model SBS-1 contains stainless steel apparatus for the filtration procedure. This apparatus is satin-finished outside and the funnel is mirror-polished inside to minimize adherence of organisms during testing. All necessary equipment for Coliform or Total Count Determinations is contained in the laboratory, including forceps, vacuum pump, bottles for sterile rinse water and reagents. The laboratory operates from any 110 volt, 60 cycle, AC electrical outlet, although converters are available for operation from automobile batteries. Nickel-cadmium batteries also may be used as a power source. In addition, motors and converters for other power

characteristics are available.

An integral part of the Sabro Laboratory is its incubator. The motor, with a squirrel cage blower, supplies both the heat and air circulation in the incubator, guaranteeing uniform temperature in the incubating chamber. The incubator drawer is magnetized so that the culture cans are held firmly in place and the drawer is held closed by magnets. Incubator temperature, held to within ± 1 F., can be checked at all times by a dial thermometer.

The disposable culture can assemblies consist of a sterile, labeled culture can containing a sterile membrane filter and a sterile absorbent pad together with a sterile ampoule filled with nutrient (M Endo Broth for coliform determinations, Brain-Heart Infusion Broth for total counts). The ampouled nutrient has a *one year shelf life* and gives outstanding colony recovery.

Use of these culture can assemblies saves time and money as it does away with the labor and breakage entailed in preparing nutrients, dish washing, tube plugging and sterilizing.

The outstanding feature of the Membrane Filter technique over the MPN (Most Probable Number) technique is that the entire incubation period is completed in approximately 18-20 hrs. Where the Membrane Filter technique is used, the Sabro Laboratory offers fast, accurate analysis as well as permanent records of each water examination.

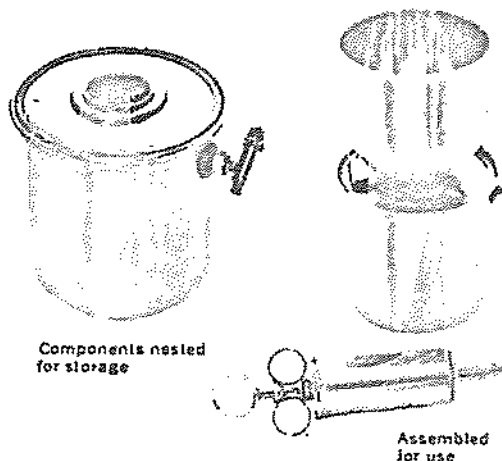
Model SBS-1 FILTRATION APPARATUS

The stainless steel testing apparatus for bacteriological analysis of water by the Membrane Filter technique is heavy-duty, high-quality laboratory equipment. Being stainless steel throughout, it is durable, unbreakable and easily cleaned. All components of the apparatus nest within the flask for storage, so that it occupies very little space.

The assembly consists of a 500 ml mirror-polished funnel, a 500 ml flask, the membrane filter holder, and a double-acting valve. The filter holder makes up the sealing lid of the flask, and in its center is mounted a porous stainless steel insert. The membrane is laid on this insert, and it is through the membrane and this insert that the water being tested must pass to get from the funnel to the flask.

The entire assembly can be flame-sanitized or sterilized in an autoclave.

The funnel is 500 ml capacity; and is locked simply and firmly to the filter holder in such a manner that it cannot damage the membrane filter.



A PARTIAL LIST OF SABRO MF EQUIPMENT USERS FOR WATER AND WASTE TESTING

U. S. Public Health Service—
all regional engineers
U. S. National Park Service
U. S. Indian Service
International Cooperation Agency (Korea,
Viet Nam, Thailand, Turkey, Iran)
U. S. Armed Forces
World Health Organization
City of Pittsburgh
City of Cleveland

State of Pennsylvania
State of Illinois
Union Carbide Corporation
University of North Carolina
W. R. Grace & Company
Gulf Oil Corporation
Philco Corporation
Radio Corporation of America
Coca-Cola International
Trans World Airlines

Hagan Corporation
Ochs Power Company
British European Airways
American Water Works Service Company
Western Electric Company
Unimatic Engineering Co.
Duquesne Light Company
General Water Works Management and
Service Company
United Nations Children's Fund (UNICEF)



IONICS, INCORPORATED

P.O. Box 99, Bridgeville, Pennsylvania 15017 (Pittsburgh District)
65 Grove Street, Watertown, Massachusetts 02172 (Boston District)

Litho U.S.A.

- If the water is to be used for drinking, it must be treated with a disinfectant.
- If the water is to be used for irrigation, it must be treated with a disinfectant.

• If the water is to be used for irrigation, it must be treated with a disinfectant.

- If a water softener is to be used, it must be installed before the HYgene unit, although it will not affect the operation of the HYgene system. Otherwise, iron/silver (the germicide) from the HYgene will be removed by the softening process.

Post-treatment is not required with HYgene as it is with chlorination. The activated carbon base of the HYgene medium also removes odors and tastes from the effluent water.

Q. How can the HYgene system be tested to be certain it is operating properly and killing the harmful bacteria?

A. There are two methods of testing the HYgene treated water:

- By bacteriological analysis to be certain the system is destroying the pathogenic, disease-carrying bacteria. This test can be run with the use of the Ionics SABRO bacteriological testing equipment or by a local testing laboratory or hospital.
- By silver residual test to determine if the purifying agent is present in sufficient quantity to give an effective kill of the bacteria. The silver concentration can be determined by the Low Range Silver Test kit manufactured by Lathrop Chemical Company of Chestertown, Maryland. This test kit is available from Ionics or Lathrop Chemical Company.



P.O. BOX 99 • BRIDGEVILLE, PA. 15017
INTERNATIONAL WATER CONSULTANTS AND
EQUIPMENT MANUFACTURERS • MEMBER WATER
CONDITIONING FOUNDATION AND THE WATER
CONDITIONING ASSOCIATION INTERNATIONAL

Litho in U.S.A. H-174

QUESTIONS & ANSWERS ABOUT



WATER PURIFICATION PROCESS

Q. What is HYgene?

A. The physical characteristics of HYgene are comparable to those of granular activated carbon upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver.

Q. How does HYgene purify water?

A. Silver, which has been chemically plated onto activated carbon, is the purifying agent. As contaminated water passes through a layer or bed of HYgene material small quantities of silver—less than 50 parts per billion (ppb)—are dissolved. It is this trace amount of silver which destroys the pathogenic organisms found in polluted water.

Q. Does silver from the HYgene process have a toxic effect on humans?

A. The silver from the HYgene process is not particularly toxic. The limitation is intended, however, to guard against argyrosis, which is only of cosmetic significance and occurs very rarely and only when strong concentrations of silver are consumed. The HYgene process produces a water effluent with such a low silver content that no toxic effect, cosmetic or otherwise, will occur.

Q. Has the Ionics HYgene process been approved by the federal and state health departments?

A. Health departments do not approve methods used for sterilizing water. Health authorities do demand that effluent water from any of the

following methods comply with its set standards, both chemically and bacteriologically. Ionics HYgene process will produce water within these acceptable standards.

The process used for water purification is an individual choice. Chlorination, ozone, iodine, ultraviolet radiation, silver filtration are some of the alternatives.

Q. How is HYgene used?

A. There are many application requirements for HYgene ranging from small field or emergency drinking water kits to large industrial/municipal water purification systems. HYgene media is most effective in a compact layer or filter bed system where the raw water passes through a column of material at a given flow rate, or for a mandatory predetermined contact time, in order to destroy bacteria.

Q. Can HYgene be used in the home?

A. The HYgene process can be used in the home for water purification. The equipment is compact and easy to install and use. The effluent water is safe for drinking and is discharged miles away, making it practically impossible to trace. When this contaminated water is recognized, the homeowner must make a choice of available means to purify the water. HYgene equipment is safe, reliable and economical for home use.

Q. Is the HYgene system a more expensive method of purifying water than chlorination?

A. Surprisingly, HYgene is generally less expensive over a given period of time. The initial cost or capital investment for either method of water purification is approximately the same. The chlorinated system, after installation, re-

quires continuous operational costs for added chemicals and frequent carbon recharging. It also demands constant maintenance such as frequent equipment adjustments and a rigid schedule of solution preparation. The HYgene system, on the other hand, operates completely free of additional chemicals and with a minimal amount of maintenance required for periodic backwash—every four to six weeks—to maintain a clean filter bed. The backwash requirements of the HYgene filter depend upon the turbidity of the raw water.

Q. What is the life expectancy of an Ionics HYgene filter?

A. The treating capacity of the HYgene filter is directly related to the amount of medium in the unit. Each cubic foot of HYgene material will sterilize 750,000 gallons of contaminated water under normal operating conditions. The total treating capacity for your HYgene water treatment system may be determined by multiplying the following equation by the number of cubic feet of HYgene material in your filter.

calculating this life expectancy is the installation of a water meter.

Q. Is a retention or holding tank necessary following the HYgene filter?

A. As with chlorination, holding time is recommended following HYgene treatment to provide residual bacteria kill.

Q. What are the filtration characteristics of HYgene?

A. The hydraulic behavior of a HYgene bed is identical to that of a comparable 12 x 30 mesh carbon filter.



GENERAL IONICS®

HYgene® WATER PURIFIER

APPLICATIONS:

- Purification of water for homes, hotels, motels, cottages, institutions, industrial plants, commercial plants, commercial buildings, shipboard, air fields, construction camps, etc.
- Slime suppressant in cooling systems and air conditioning systems.

OPERATION:

The HYgene® Process kills water-borne intestinal disease carrying bacteria such as those producing typhoid, paratyphoid, cholera, bacillary dysentery and other such diseases spread by drinking water. The purifying agent employed is a silver salt of complex chemical structure which is deposited on activated carbon. While the silver purifies the water, the activated carbon in the system improves the taste, odor and color. Trace amounts of silver released into the water continue to maintain purity long after it passes through a HYgene® filter bed. HYgene® will purify any water which is "bacteriologically accepted for treatment" as defined by the United States Public Health Service Manual, RECOMMENDED WATER-SANITATION PRACTICE. A 10 to 30 minute holding period of the HYgene® system effluent is recommended to insure 100% kill.

ADVANTAGES & FEATURES:

- Pure, odorless, sparkling clear water.
- No additions of chemicals required.
- Non-irritating to eyes and mucous membranes.
- Unaffected by exposure to light.
- Unaffected by exposure to increased temperature.
- Simple and economical to install and maintain.
- No moving mechanical parts to maintain.
- Periodic backwash keeps system functioning properly.
- Produces potable water to meet U.S. Public Health standards.

RAW WATER LIMITATIONS:

For reliable operation of the HYgene® system, the following are raw water limitations:

Chlorides: 500 ppm maximum

Sulfates: 2000 ppm maximum

Iron: 2 ppm maximum. Most raw waters high in iron content can be pre-treated for its removal before HYgene® treatment.

Color: 20 ppm maximum

Turbidity: 5 ppm maximum

pH: 5.0 to 8.5

Temperature: 40 F to 85 F

Hydrogen Sulfide: If present, its removal is recommended.

HYgene® Specifications

Model	Flow Rate max. gpm	Treating Capacity gallons	Oper. Pressure PSI	HYgene® Mineral cu. ft.	Unit Dimen. Hgt.	Flr. Sp.	Recommended Size for holding tanks
HY45	4.5	750,000	20-100	1.5	60"	10"x20"	80 to 150 gal.
HY90	9.0	1,500,000	20-100	3.0	65"	14"x25"	150 to 300 gal.

Fiberglass Tank Specifications: HYgene® pressure tanks are made of fiberglass material. These units are available from stock in the two sizes listed above. Purifying units of greater capacity or a special design to meet unusual flow or application requirements can be supplied.

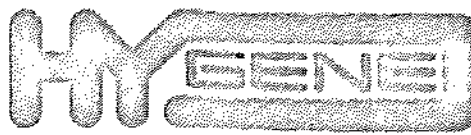
*NOTE: When installed and operated according to specifications, water treated by the HYgene® Process will meet the bacteriological standard for potable water as established by the U.S. Public Health Service.

Holding Tanks: Storage tanks may be purchased from Ionics, Inc. or from your local supplier.

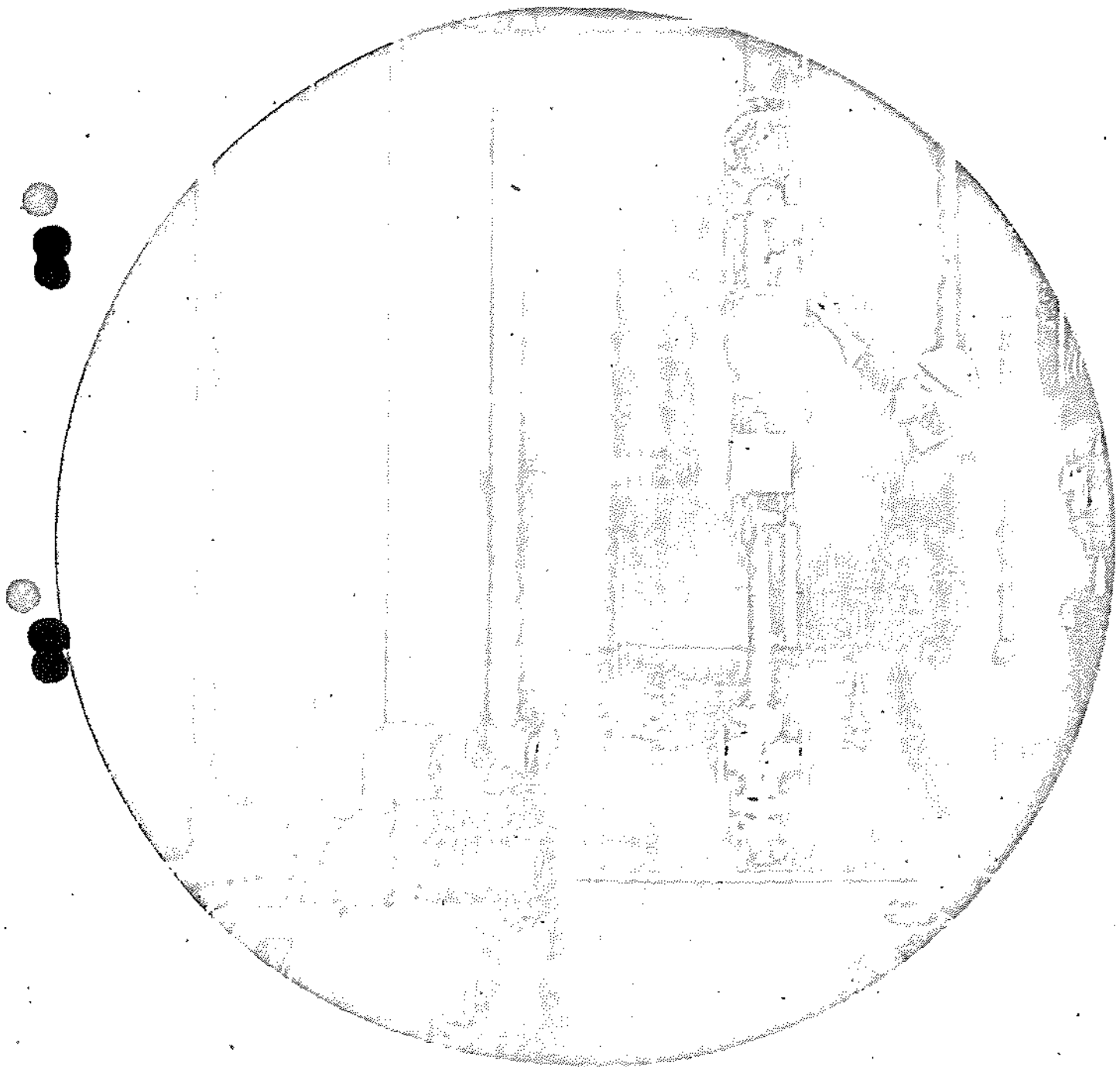
IONICS, INCORPORATED

MANUFACTURERS OF GENERAL IONICS® WATER CONDITIONERS
P. O. BOX 99 • BRIDGEVILLE, PENNSYLVANIA 15017 (Pittsburgh District)
INTERNATIONAL WATER CONSULTANTS AND EQUIPMENT MANUFACTURERS
Member Water Conditioning Foundation and Water Conditioning Association International

HYgene



WATER PURIFIERS
SILVER/ACTIVATED CARBON FILTRATION SYSTEMS
TO PRODUCE SPARKLING BACTERIOLOGICALLY PURE WATER





WATER PURIFIERS

...SET NEW STANDARDS FOR SAFETY

In the silver/activated carbon system the silver purifies the water while the activated carbon removes objectionable taste, odor and color. Additionally, HYgene purified water is unaffected by sunlight or temperature increase, and the silver ions also provide a residual effect to maintain water purity long after passing from the filter bed.

Sabro bacteriological testing

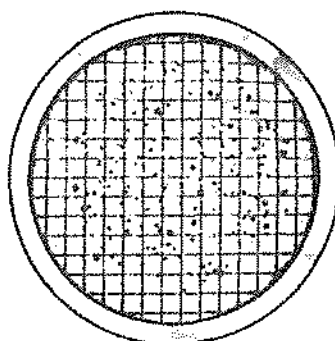
The Ionics SABRO Portable Laboratory provides equipment necessary for the bacteriological examination of water. This membrane filter (MF) technique used by SABRO has been given the status of a Standard Procedure in American Public Health Association's *Standard Methods*. The SABRO MF method offers fast, accurate analysis as well as a permanent record of each water examination.

SABRO Portable Laboratories are in continual use by Pennsylvania and other state Departments of Health and Environmental Engineering, U. S. National Park Service, U. S. Indian Service, U. S. Armed Forces, International Cooperation Agency and the World Health Organization.

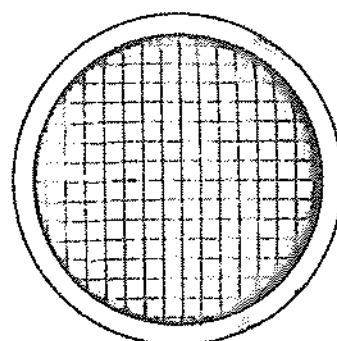
Raw water limitations for HYgene

Reliable long-term operation of HYgene water purifiers can be expected if the process is kept within the following raw water limitations:

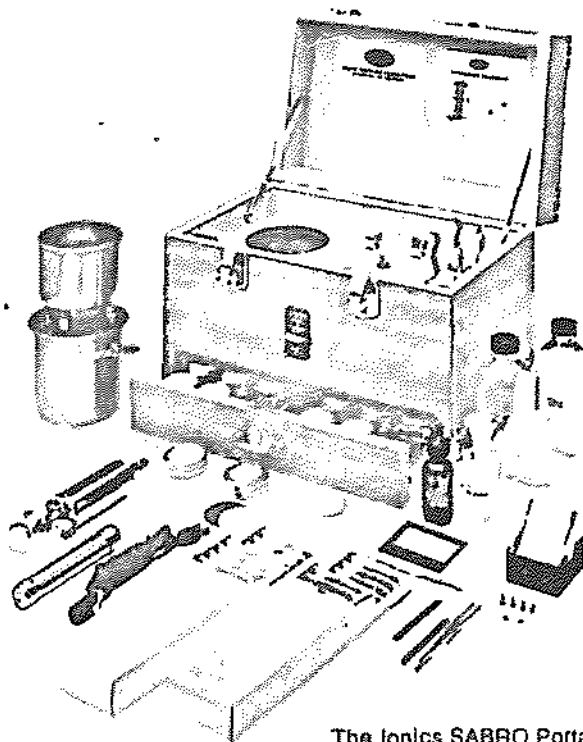
Chlorides.....	500 ppm maximum
Sulfates.....	2000 ppm maximum
Iron.....	0.2 ppm maximum . . . most raw waters high in iron content can be pretreated for its removal before HYgene treatment
Color.....	20 ppm maximum
Turbidity.....	5 ppm maximum
pH.....	5.0 to 8.5
Temperature.....	40°F to 85°F
Hydrogen Sulfide.....	If present, its removal is recommended



Before HYgene treatment the coliform culture shows pathogenic disease-carrying bacteria in raw water supply.



After HYgene treatment the clear culture above indicates the bacteria have been destroyed.



The Ionics SABRO Portable Laboratory using the membrane filter technique is in daily use throughout the world.



IONICS, INCORPORATED

P. O. Box 99 • Bridgeville, Pennsylvania 15017
International Water Consultants and Equipment Manufacturers



WATER TREATMENT SYSTEM...POLISHES AS IT PURIFIES

The HYgene water purifier is a silver disinfectant process that will purify any water bacteriologically acceptable for treatment as defined by the United States Department of Health Service Manual. The system is particularly effective as a disinfecting process against pathogenic intestinal organisms found in water, including germs that cause typhoid fever, dysentery, cholera and diarrhea.

In addition to its purifying qualities, HYgene units filter the water and remove objectionable taste, odor and color without the use of chlorine or other chemicals.

Filtration/flow rate capacities

Under normal operating conditions HYgene water purifiers will treat an average of 750,000 gallons of raw water per cubic foot of mineral. HYgene units are designed for a flow rate of 3 gallons per minute per cubic foot of purifying agent.

A simple backwashing of the unit is all that is necessary to keep HYgene functioning properly and maintain its purifying, polishing and filtration efficiency.

Operation

The principle of the HYgene process is silver ions deposited on an inert carrier in an oligodynamic or finely divided form in such a way that the solubility is limited to meter trace quantities. Contaminated water contacting the purifying agent dissolves very minute quantities of silver. The trace amounts of silver released into the water purifies and continues to maintain purity long after the water passes through the filter bed.

A storage reservoir following the filtration bed is recommended. A 10- to 30-minute holding period of the HYgene system effluent is sufficient to insure a 100% kill. The effluent is unaffected by exposure to light or increased temperature.

Standard sizes and specials

Ionics manufactures standard HYgene fully automatic equipment for maximum daily production rates from 20,000 gallons up to 210,000 gallons. Larger units of special design and capacities can be engineered and manufactured by Ionics. Under average conditions the treating capacity of the purifying agent can run from 4 million gallons in the HY-160 model to 36 million gallons in the HY-1470.

In addition to these commercial/industrial sizes, Ionics manufactures two domestic units with capacities of $\frac{3}{4}$ million and $1\frac{1}{2}$ million gallons.

HYgene fully automatic industrial/municipal potable water treatment systems

Model	Flow Rate Maximum (GPM)	Treating Capacity (Gallons Per Charge)	HYgene Mineral (Cu. Ft.)	Max. Daily Production (Gals/24 Hrs. @ Max. Rate)	Unit Dimension				Recommended Nominal Holding Tank Size (Gallons)
					Hgt.	Floor Space L x W	Tank Diameter	Valve & Pipe Size	
HY-160	16	4,000,000	5.5	20,000	64"	24" x 34"	20"	1 $\frac{1}{4}$ "	500
HY-240	24	6,000,000	8.0	30,000	66"	28" x 40"	24"	1 $\frac{1}{4}$ "	750
HY-360	36	9,000,000	12.0	50,000	68"	34" x 46"	30"	1 $\frac{1}{2}$ "	1100
HY-540	54	13,500,000	18.0	75,000	70"	36" x 52"	36"	2"	1600
HY-720	72	18,000,000	24.0	100,000	72"	42" x 68"	42"	2"	2200
HY-960	96	24,000,000	32.0	130,000	74"	48" x 74"	48"	2 $\frac{1}{2}$ "	3000
HY-1200	120	30,000,000	40.0	170,000	76"	54" x 89"	54"	2 $\frac{1}{2}$ "	3600
HY-1470	147	36,000,000	49.0	210,000	78"	60" x 95"	60"	2 $\frac{1}{2}$ "	4500

Reliability

A major part of the research and development investigation on the behavior of disinfection with silver was carried out at the Johns Hopkins University Department of Sanitary Engineering under the direction of Dr. Charles E. Renn. Also, Ionics Quality Control Department continually checks the physical and chemical characteristics of HYgene mineral to assure that the special properties are maintained.

HYgene completely automatic units mean just that. Water purifiers installed in the United States and elsewhere have produced remarkable records of trouble-free performance involving many sources of water.

HYgene advantages vs. chlorination

The HYgene system of water purification has a number of advantages over conventional chlorination systems.

Characteristic	HYgene	Chlorination
Medicinal Taste	None	Yes
Objectionable Odor	None	Yes
Handling of Dangerous Chemicals	No	Yes
Irritation to Eyes and Mucous Membranes	None	Yes
Affected by Sunlight	No	Yes
Loss of Residual Effectiveness	No	Yes

In addition to these considerations, over-all cost is a major concern. On a strict comparison of equipment costs the chlorination process appears less expensive. However, when real maintenance and plant operation expenses are considered, the HYgene treatment becomes quite competitive. As an example, the HYgene system

eliminates the purchasing, storage and handling of potentially dangerous chemicals.

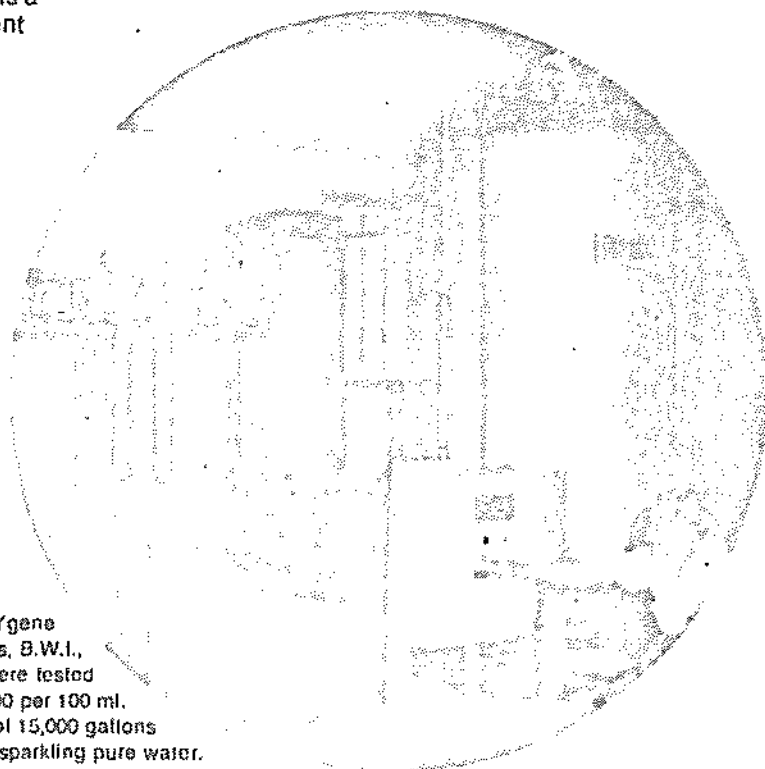
Commercial and industrial chlorination systems demand the attention of an operator to continually monitor chlorine feed as well as switch the spent chlorine tanks. In most cases these assignments involve one extra man on the work force. HYgene units at the same installation eliminate this costly overhead burden. All that is required of the HYgene system is a periodic backwashing to keep the unit dispensing silver at a predictable rate.

Applications

The front cover illustration of this brochure is a HYgene water purification plant built for United Engineers & Constructors at Martins Creek, Pennsylvania, site of a new power plant for Pennsylvania Power & Light Company. This treatment facility turned bacteriologically contaminated well water into potable drinking water in excess of 100,000 gallons per day.

Practically speaking, most any residential home, commercial, industrial and institutional plant or small municipality can take advantage of the HYgene water purification process. Here are a few examples:

Air Fields	Industrial Plants
Commercial Plants	Institutions
Construction Camps	Motels
Cottages	Office Buildings
Homes	Shipboard
Hotels	



One of three fully automatic HYgene water purification systems installed in the Bahamas, B.W.I., where pathogenic intestinal organisms were tested and found to average 10,000 per 100 ml. Each unit produces a maximum of 15,000 gallons per day of sparkling pure water.

Enclosure # 9 (b)

2/17/75

Enclosure

9 (b)

As the day of the week is not specified, the date is not known.

Enclosure # 9 (a)

2/27/75

Enclosure # 9 (a)



WATER PURIFICATION MEDIA

- Disinfects without the use of chlorine
- Produces potable water to meet USPH standards
- Removes objectionable taste, odor and color

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and chemical fumes.

Active Ingredient - Metallic Silver	1.05%
Inert Ingredient - Activated Carbon	98.05%

Contents: _____ cu. ft. Lot No. _____
Code _____

• Another fine product by the manufacturers of General Ionics Water Conditioning Equipment

IONICS, INCORPORATED / Routes 519 & 50, Bridgeville, Pennsylvania 15017

® Trademark registered

FIELD BRANCH RETURN

DATE: IN _____ OUT _____ IN _____ OUT _____ IN 9/25/75 OUT 9/30/75
FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 35900-E

PERMIT OR EXP. PERMIT NO. _____

DATE DEV. RECEIVED 9/5/75

DATE OF SUBMISSION 9/3/75

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): I, (D,) H, P, N, R, S Self-sanitizing filter media

PRODUCT REG. NO. 33

PRODUCT NAME(S) Hygene Self-sanitizing Water Filter Media

COMPANY NAME Ionics, Inc.

SUBMISSION PURPOSE Resubmission with data

CHEMICAL & FORMULATION metallic silver 1.05%

200.0 Introduction

200.1 Use: Self-sanitizing Water Filter Media

201.0 Data Summary

201.1 Abstract of test reports: Thirteen test columns (2" I.D. and 12" ht.), each containing 250 cc of filter media for a bed depth of about 5" per column, were challenged intermittently to 2000 gallons of dechlorinated tap water at a flow rate of 500 ml per minute. Ten columns were used for chemical determinations of silver release in the effluent. Bacteriological testing was conducted with the other three test columns and three control columns, containing 250 cc of untreated activated carbon which were tested simultaneously with test columns. Each column was challenged with 120 ml (approximate void bed volume) of dechlorinated tap water seeded with Escherichia coli and allowed to remain in contact with the filter bed for 10 hours before the columns were drained and the effluent assayed.

201.1.1 Brief description of tests: The chemical determinations for silver were done by the Atomic Absorption Method. The bacteriological samples were placed in an unspecified neutralizing solution and assayed by an undisclosed bacteriological method.

201.1.2 Data summaries: The bacteriological data provided for a 10-hour holding period are indicated below:

Sample Source	E. coli/ml
Challenge dosage	410
Filter media #05125	0.02
Filter media #04075	<0.01
Filter media #03105	<0.01
Control carbon #1	140
Control carbon #2	330
Control carbon #3	120

Note: The silver content in the effluent during the 2000-gallon challenge of water ranged from 23 to 48 ppb; the silver content in the effluent used for bacteriological testing was not determined.

The chemical data provided for the 10 units are summarized below:

Sampling Time	ppb Ag
5 gal. challenge	43-52
500 gall. challenge	33-40
After 18-hr. holding period	42-48
1200 gal. challenge	21-31
2000 gal. challenge	22-28

pH of water = 7.4-7.6; temperature = 23-24°C; flow rate; 500 ml/min.

202.0 Recommendations

202.1 Claims supported by data: The requirement to demonstrate that the silver concentration of the effluent water does not exceed 50 ppb after treatment is fulfilled by the chemical data provided.

202.2.2 Data not appropriate: The bacteriological data are inappropriate to support a self-sanitizing claim for filter media. To support such a claim, a study must be designed to demonstrate (1) that the filter media does retain bacteria in sufficient number and (2) that the filter media does effectively and significantly reduce the bacterial population retained.

202.2.3 Lesser claim the data will support: The data provided suggest inhibition of bacterial growth in water stagnated within the filter media for 10 hours. However, a conclusive evaluation of these data is prohibited because adequate control data and bacteriological test procedures were not provided.

202.3 Additional ^{information} ~~data~~ required: To substantiate the bacteriostatic claim for the filter media, the following ~~data~~ ^{additional information} must be provided: (1) Assays of the bacterial challenge dosage are required both at the beginning of the test and after the 10-hour holding period to ascertain the degree of natural "dieoff" for the bacterial aqueous suspension; (2) Assays of the effluent from the product media and the carbon control are required immediately after the bacterial challenge as well as after the 10-hour holding period to verify the effect of the holding period; and (3) determinations of the silver content in the effluent at these sampling times are required to verify that the bacteriostatic effectiveness of the filter media is based on a silver concentration which is less than 50 ppb. Include bacteriological test procedures with these test results.

203.0 Labeling

The following labeling revisions are required: 1) Concentration of inoculation at end of test
2) The neutralizer used.
3) Conc. of Ag in 3 test units used for bacteriological
4) Count procedures for 3 test and 3 control units.

1. Change "Self-sanitizing" to read "bacteriostatic"

2. Change the claim "Prevents the growth of bacteria" to read

*Amended
10/7/76
E. J. Brown
Chief
Desiccation Dept.*

"Inhibits the growth of bacteria."

3. Delete "as a sanitizer."
4. Provide the necessary calculations to verify that the flow rate recommended on the label is comparable to the flow rate used in these laboratory experimentation studies.

Any collateral literature, such as technical bulletins or brochures, distributed in conjunction with this product must be submitted for review.

Dorothy M. Portner

Dorothy M. Portner

9/30/75

Efficacy Section

Efficacy and Ecological Effects Branch



SELF-SANITIZING WATER FILTER MEDIA

- Prevents the growth of bacteria
- Removes objectionable taste, odor and color

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and chemical fumes.

EPA Reg. No. _____

EPA Est. No. 35900 PA 01

ACTIVE INGREDIENT

METALLIC SLIVER _____ 1.05% LOT NO. _____

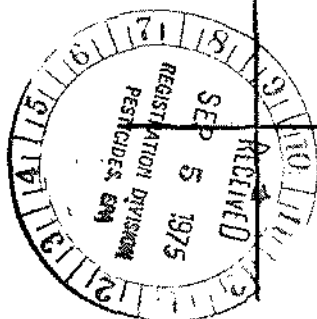
INERT INGREDIENT

ACTIVATED CARBON _____ 98.95% NET CONTENTS _____ cu. ft.

DIRECTIONS FOR USE AS A SANITIZER: Flow rate is not to exceed 15 GPM per cu. ft. of media. Bed depth must be at least twice the diameter.

DISPOSAL OF SPENT MEDIA: _____ Retain shipping carton and plastic liner for disposing of exhausted filter media with trash.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment
IONICS, INCORPORATED Routes 519 & 50, Bridgeville, Penna. 15017



Handwritten: 2. J. Bonious
9-3-75

**IONICS****IONICS, INCORPORATED**P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A.C. 412 343-1040 TWX 5106673299

September 3, 1975

AIRMAIL SPECIAL DELIVERYCERTIFIED MAIL - RETURN RECEIPT REQUESTED - ADDRESSEE ONLY

Mr. James H. Banks - PM 33
United States Environmental Protection Agency
Disinfectants Branch, Room 321
Registration Division (WH-567)
OPP-EPA
401 M Street S.W.
Washington, D. C. 20640

Subject: HYGENE
Ionics File Symbol 85900-E
Ionics Application of February 10, 1975

Dear Mr. Banks:

Enclosed with this letter are our test results on "Evaluation of HYGENE Product Media for EPA Registration". This testing procedure was performed in accordance with instructions from Mr. E. F. Brown, Chief - Disinfectants Branch, Environmental Protection Agency.

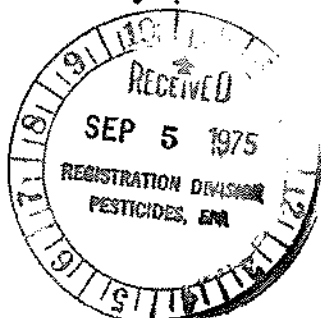
It is our understanding from our conversations with Mr. Brown that if our test results show that we kill more than 90% of the coliform, our EPA rating would be as a self sanitizer. If we were to kill less than this, we would receive a bacteriostatic rating.

We have also enclosed a copy of the letter we received from you dated July 25, 1975 and received in our office on July 30, 1975. This gave us the guide lines for our testing which was later supplemented by our instructions from Mr. Brown.

This letter also gave us guide lines for our labeling and five copies of our proposed labeling are enclosed.

We respectfully request your urgent evaluation of the enclosures along with our previous data since we are at present under a "Stop Shipment Notice" from your enforcement division.

If there are any questions at all concerning this data, please contact me.



Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle
Enclosures
cc: J. D. Collins

**IONICS****IONICS, INCORPORATED**P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

September 3, 1975

AIRMAIL SPECIAL DELIVERYCERTIFIED MAIL - RETURN RECEIPT REQUESTED - ADDRESSEE ONLY

Mr. James H. Banks - PM 33
United States Environmental Protection Agency
Disinfectants Branch, Room 321
Registration Division (WH-567)
OPP-EPA
401 M Street S.W.
Washington, D. C. 20640

Subject: HYGENE
Ionics File Symbol 359D0-E
Ionics Application of February 10, 1975

Dear Mr. Banks:

Enclosed with this letter are our test results on "Evaluation of HYGENE Product Media for EPA Registration". This testing procedure was performed in accordance with instructions from Mr. E. F. Brown, Chief - Disinfectants Branch, Environmental Protection Agency.

It is our understanding from our conversations with Mr. Brown that if our test results show that we kill more than 90% of the coliform, our EPA rating would be as a self sanitizer. If we were to kill less than this, we would receive a bacteriostatic rating.

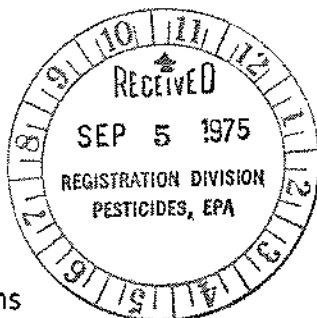
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This letter also gave us guide lines for our labeling and five copies of our proposed labeling are enclosed.

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Very truly yours,

IONICS, INCORPORATED
Bridgeville PlantWalter J. Polens
Vice President

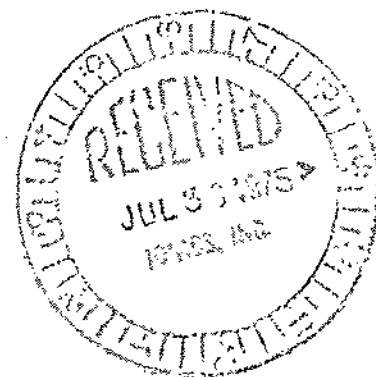
WJP:mle
Enclosures
cc: J. D. Collins



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
REGISTRATION DIVISION

IONICS, INCORPORATED
Attn: Walter J. Polens
P.O. Box 99
Bridgeville, PA 15017

JUL 25 1975



Gentlemen:

Subject : HYGENE
File Symbol 35900-E
Your application of February 10, 1975

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable, for the reasons given below.

1. The data submitted do not support claims of efficacy for this product as a water purifier. Submit chemical and bacteriological data developed in accordance with the procedures outlined in Part VII A and B of the document "Interim Standards for Water Purifier" enclosed herein.
2. Submit labeling amended to include only bacteriological efficacy claims delineated in Part VI of this document.
3. The labeling submitted must be amended to include mandatory labeling requirements as indicated below:

A. On the front panel:

1. An acceptable product name. (The present name is acceptable)
2. The ingredient statement must appear on the front panel, or that part of the label displayed under customary conditions of purchase. Also, the ingredient statement must be clear on a contrasting background, not obscured or crowded.
3. The word "CAUTION" followed by the referenced "Keep Out of Reach of Children" Note: These must appear in proper type size as indicated on the "Front Panel Precautionary Labeling Requirements" enclosure.
4. A statement of net contents, as for example "Net Contents: 1 water purifier unit."

B. The following may appear elsewhere on the label:

1. The name and address of the registrant.
2. A container disposal statement somewhat as "Wrap spent purifier unit in newspaper and discard with trash."
3. Directions for use or a statement setting forth where such directions may be found such as "See enclosed circular (or leaflet or bulletin) for directions for use."
4. The assigned EPA Reg. No.
5. The EPA Est. No.

This product may not be lawfully distributed in interstate commerce until it is registered.

Sincerely,

James H. Banks
for

James H. Banks
Product Manager 33
Disinfectants Branch (WH-567)

Enclosure

REGISTRATION DIVISION

IONICS, INCORPORATED
Attn: Walter J. Polans
P.O. Box 99
Bridgeville, PA 15017

Gentlemen:

Subject : HYGENE
File Symbol 35900-E
Your application of February 10, 1975

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Sincerely,



James H. Banks
Product Manager 33
Disinfectants Branch (WH-567)

Enclosure

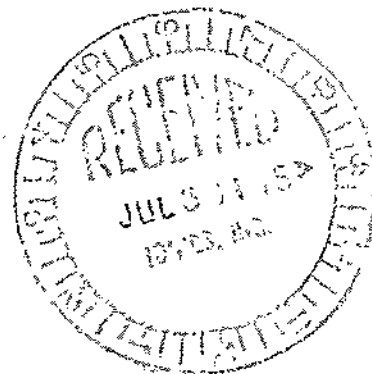
WH-567:DIS:RGD:md:7-23-75:59040:Rm 321



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
REGISTRATION DIVISION

IONICS, INCORPORATED
Attn: Walter J. Polens
P.O. Box 99
Bridgeville, PA 15017

JUL 25 1975



Gentlemen:

Subject : HYGENE
File Symbol 35900-E
Your application of February 10, 1975

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable, for the reasons given below.

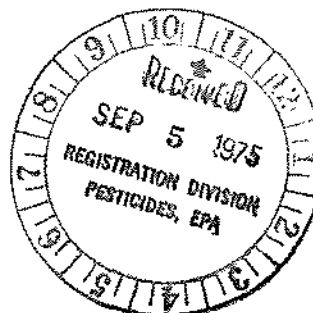
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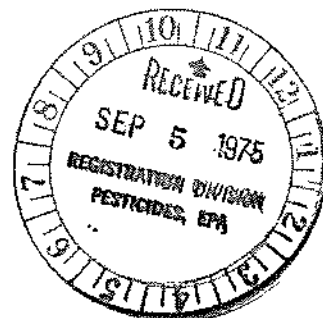
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Sincerely,

James H. Banks

James H. Banks
Product Manager 33
Disinfectants Branch (WH-567)

Enclosure



2-A _____ 2-B _____ 2-C ☒ Review under revised Sec. 3 Reg. Yes _____ No _____

Date of Submission: 11-13-75 Reg/EXP 35900 2 Petition No. _____
Product Name H490116
Company _____

Type of Product: I R H F D

Product Manager (name): _____

Type Submission-
Rm# _____

Petition

New Product -New Chem. _____

New Product Old Chem _____

Amended Reg. Substantive _____

Amended Reg. Nonsubstantive _____

Reviews Needed	Rec'd by E. Gross	Sent to Reviewer	Date Completed	Returned to PM
RET				

Completeness Review _____ Data Review ☒ Waiver Reg. _____

Review Labeling

Letter information submitted in reference to
37756-R.
EEEB

EFFICACY

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling

Letter

F&W

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling

Letter

ENV. CHEM.

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling

Letter

TOX BR.

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling

Letter

CHEM BR.

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling

Letter

2-A

2-B

2-C

Review under revised Sec. 3 Reg. Yes No

Date of Submission: 12-3-75 Reg/EXP NA

Petition No. _____

Product Name HV2 Water CleanerCompany Lonics Inc.Type of Product: I R H F DProduct Manager (name): BanksType Submission- New ProductRm# 321

Petition

New Product -New Chem. _____

New Product Old Chem _____

Amended Reg. Substantive _____

Amended Reg. Nonsubstantive _____

Reviews Needed

Rec'd by E. Gross

Sent to Reviewer

Date Completed

Returned to PM

RET

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling _____

Letter _____

EEEB

EE: UCYCompleteness Review X Data Review _____ Waiver Reg. _____

Review Labeling _____

Letter Comment on Mr. of 12-3-75

F&W

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling _____

Letter _____

E: CHEM.

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling _____

Letter _____

TOX BR.

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling _____

Letter _____

CHEM BR.

Completeness Review _____ Data Review _____ Waiver Reg. _____

Review Labeling _____

SUBMISSION REVIEW RECORD			1. REGISTRATION NUMBER		CYCLE	2. DATE RECEIVED		
3. 3CID PUBLICATION NECESSARY <input type="checkbox"/> YES <input type="checkbox"/> NO			4. PETITION NO.			5. RECEIVED PM TEAM		
6. METHOD OF SUPPORT <input type="checkbox"/> 2A <input type="checkbox"/> 2B <input checked="" type="checkbox"/> 2C			7. PRODUCT MANAGER <i>James H. Banks</i>		NO.	8. PROJECTED RETURN		
9. DATE PULLED		10. DATE PUBLISHED	11. ACTION TYPE			12. OUTGOING DATE		
		<i>3-24-75</i>	<i>Resubmission - data</i>		<i>32</i>			
REV. SEC.	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COM-MENT CODE	DATE REVIEW COMPLETED			
					MO	DAY	YR	
A	REVIEWABILITY TEAM							
B	PRODUCT MANAGER TEAM EFFICACY REVIEW							
C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW							
D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW							
E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW							
F	PRODUCT MANAGER							
G	INTERAGENCY REFERRAL							
H	COST-BENEFIT REVIEW							
I	PUBLIC COMMENTS REVIEW							
J	EEE BRANCH INSECTICIDE EFFICACY							
K	EEE BRANCH HERBICIDE EFFICACY							
L	EEE BRANCH FUNGICIDE EFFICACY							
M	EEE BRANCH RODENTICIDE EFFICACY							
X	N EEE BRANCH DISINFECTANT EFFICACY	<i>DMIP</i>	<i>DM Portner</i>		<i>1</i>	<i>0</i>	<i>23</i>	
	O CHEMISTRY BRANCH RESIDUE CHEMISTRY							
	P EEE BRANCH ENVIRONMENTAL CHEMISTRY							
	Q TOXICOLOGY BRANCH HUMAN SAFETY							
	R EEE BRANCH ENVIRONMENTAL SAFETY							
	S							
	T							
PRODUCT MANAGER SIGNATURE			TYPE OF RESPONSE			CODE		
<i>Keith Douglas for JHB</i>			<i>Registration Notice</i>			<i>R-2</i>		

EEE REVIEW REVIEW

DATE: IN _____ OUT _____ IN _____ OUT _____ IN 10/21/75 10/23/75
FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 35900-E

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 10-17-75

DATE OF SUBMISSION 10-14-75

DATE SUBMISSION ACCEPTED _____

DATE PRODUCT(S): I, (D), H, F, N, R, S Bacteriostatic Water Filter Media

PRODUCT REG. NO. 33

PRODUCT NAME(S) Hygene

COMPANY NAME Ionics, Incorporated

SUBMISSION PURPOSE Resubmission with data

CHEMICAL & FORMULATION Metallic Silver 1.05%

- 200.0 Introduction
- 200.1 Use: Bacteriostatic Water Filter Media
- 200.1.1 Background information: This submission includes information requested in our letter of October 9, 1975.
- 201.0 Data Summary
- 201.1 Abstract of test report: The concentration of the artificially contaminated water used to challenge the units averaged 410 E. coli per ml; after sitting 24 hours, the concentration of this artificially contaminated water also averaged 410 E. coli per ml according to Linda Deans, who was responsible for the testing. No determination was made for the silver content in the effluent which was assayed for bacteriological efficacy. However, since the chemical data provided to demonstrate silver release did not exceed 50 ppb, it will be assumed that the silver concentration in the effluent used in the bacteriological assays also did not exceed 50 ppb.
- 202.0 Recommendations
- 202.1 Claims supported by data: The information provided fulfill the request indicated in our letter of October 9, 1975.
- 203.0 Labeling
- Revise the first two paragraphs of the letter to be sent to your customers to read: "This letter is to inform you that Ionics, Incorporated has a bacteriostatic water filter media product, Hygene, EPA Reg. No. 35900-2."
- "Hygene has been laboratory tested to demonstrate bacteriostatic activity. The filter media will inhibit the growth of bacteria which is entrapped during the treatment of water."

Dorothy M. Portner

Dorothy M. Portner
Efficacy Section
Efficacy and Ecological Effects Branch

10/23/75

SUBMISSION REVIEW RECORD		1. REGISTRATION NUMBER		CYCLE	2. DATE RECEIVED			
G 35900 -		E			MO	DAY	YR	
3. 3CID PUBLICATION NECESSARY <input type="checkbox"/> YES <input type="checkbox"/> NO		4. PETITION NO.			5. RECEIVED PM TEAM MO DAY YR			
6. METHOD OF SUPPORT <input type="checkbox"/> 2A <input type="checkbox"/> 2B <input checked="" type="checkbox"/> 2C		7. PRODUCT MANAGER James H. Banks		NO. 33	8. PROJECTED RETURN MO DAY YR			
9. DATE PULLED	10. DATE PUBLISHED 3-24-75	11. ACTION TYPE Resubmission		CODE 52	12. OUTGOING DATE MO DAY YR			
REV. SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COM. MENT CODE	DATE REVIEW COMPLETED MO DAY YR		
	A	REVIEWABILITY TEAM				05	16	75
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW				09	18	75
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW						
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW						
	F	PRODUCT MANAGER						
	G	INTERAGENCY REFERRAL						
	H	COST-BENEFIT REVIEW						
	I	PUBLIC COMMENTS REVIEW						
	J	EEE BRANCH INSECTICIDE EFFICACY						
	K	EEE BRANCH HERBICIDE EFFICACY						
	L	EEE BRANCH FUNGICIDE EFFICACY						
	M	EEE BRANCH RODENTICIDE EFFICACY						
✓	N	EEE BRANCH DISINFECTANT EFFICACY	DMP	DM. Portner		019	310	75
	D	CHEMISTRY BRANCH RESIDUE CHEMISTRY						
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY						
	Q	TOXICOLOGY BRANCH HUMAN SAFETY						
	R	EEE BRANCH ENVIRONMENTAL SAFETY						
	S							
	T							
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE		CODE		



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

• Conditioning Equipment • Custom Fabrication for the Nuclear, Chemical & Food Industries • Heat Transfer Equipment

July 21, 1975



Mr. James H. Banks, Products Manager 33
Disinfectants Branch (WH-567)
United States Environmental Protection Agency
Registration Division
1 M Street S.W.
Washington, D. C. 20460

Dear Mr. Banks:

This morning I received a phone call from [REDACTED]

[REDACTED] informed me that he had a meeting with EPA in Washington on Friday, July 18, 1975. They informed him that he must list the active and inactive ingredients in his product along with the formulation.


This letter is to inform you that [REDACTED] uses our HYgene in his product and we would allow you to refer to our File No. 35900-E for HYgene for this information. It is my understanding that this information, however, will be kept confidential.

I hope this gives you the information you need to allow [REDACTED] to complete the registration.

If you have any questions on any of this, please feel free to contact me.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant


Walter J. Polens
Vice President

WJP:mle

cc: [REDACTED]

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION
WASHINGTON, D.C. 20460

APPLICATION FOR **NEW** REGISTRATION OF A PESTICIDE

(Under the Federal Insecticide, Fungicide, and Rodenticide Act)

1. DATE OF APPLICATION

February 10, 1975

2. NAME OF PESTICIDE (Must be same product name as on label-do not list active ingredients)

HYgene™

IMPORTANT: READ INSTRUCTIONS ON REVERSE

3. TYPE OF PESTICIDE (Check each applicable item for combination products)

INSECTICIDE ☐ FUNGICIDE ☐ HERBICIDE ☐
RODENTICIDE ☐ GERMICIDE-DISINFECTANT ☒

OTHER (Specify)

4. NAME & MAILING ADDRESS OF FIRM TO WHOM REGISTRATION IS TO BE ISSUED
(Include Zip Code)

Ionics, Incorporated
P.O. Box 99
Bridgeville, Penna. 15017

5. IS THE REGISTRANT SHOWN IN ITEM 4 THE MANUFACTURER?

YES ☒ NO ☐

(If "No", see instruction 5 on reverse)

6. TYPE OF FORMULATION

DUST ☐ WETTABLE POWDER ☐ PRESSURIZED PRODUCT ☐
GRANULAR ☒ EMULSIFIABLE LIQUID ☐ BAIT ☐

OTHER (Specify)

7. TYPE OF CONTAINER

METAL ☒ GLASS ☐
PLASTIC ☒ PAPER ☒

OTHER (Specify)

8. NET CONTENTS OR CONTAINER SIZES

From 1 - 150 lbs.

9. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT

LITHOGRAPHED ☐ PAPER, GLUED ☒ STENCILED ☐

OTHER (Specify)

10. PLACE WHERE DIRECTIONS FOR USE APPEAR

ON LABEL ☐ IN PRINTED MATTER ACCOMPANYING PRODUCT ☒

11. DATA SUBMITTED WITH THIS APPLICATION (Identify and submit in triplicate)

EFFICACY DATA ☒ TOXICOLOGY DATA ☒ RESIDUE DATA ☐ PETITION FOR TOLERANCE ☐
OTHER (Specify):

12. ANY ADDITIONAL PERTINENT INFORMATION (Do not enter confidential formula here-see item 13, below)

Hyla 603-KM and HYgene™ reference trade names for the same product

R 4023

13. THE FOLLOWING MUST BE SUBMITTED WITH APPLICATION

- Five (5) copies of proposed labeling, including all printed or graphic matter which may accompany the sale of this product. Copies must be clearly legible and identical.
- Five (5) copies of the complete formula, showing the precise name and percentage of each active and each inert ingredient. (This information is treated confidentially.)

14. SIGNATURE OF AUTHORIZED FIRM REPRESENTATIVE

Walter J. Polens

Walter J. Polens

15. TITLE

Vice President

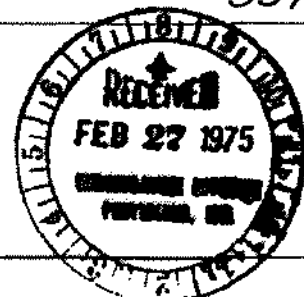
16. DATE SIGNED

2/10/75

17. RECEIVED BY EPA-ABP/REGISTRATION DIVISION, WASHINGTON, D.C. 20250

IN ANY CORRESPONDENCE ON THIS PRODUCT, REFER TO THIS FILE SYMBOL NO.:

35900-E





5H5079

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

Water Conditioning Equipment • Custom Fabrication for the Nuclear, Chemical & Food Industries • Heat Transfer Equipment

Date: February 12, 1975

Name of Petitioner: Ionics, Incorporated

Post Office Address: P. O. Box 99; Bridgeville, Penna. 15017

Date: February 12, 1975

Name of food additive and proposed use: Hygene - Used as a water purification media in systems for drinking water purifiers.

Environmental Protection Agency
Registration Division
WH567
401 M Street, S.W.
Washington, DC 20460



Gentlemen:

The undersigned, Ionics, Incorporated, submits this petition pursuant to Section 409 (b) (1) of the Federal Food, Drug, and Cosmetic Act with respect to HYgene Purification Media and Systems for Drinking Water Purifiers.

Attached hereto in triplicate, and constituting a part of this petition, are the following:

1. Technical Bulletin - Hygene Water Purification Process - Description of Material and Design Practice 5/15/73
2. HYgene Manufacturing and Quality Control (Manufacturing Procedure and Formulation), Note: This is proprietary information.
3. HYgene Quality Control Testing Procedure
4. Low Range Silver Test Procedure
5. SABRO Laboratory for Bacteriological Analysis of Water - Specification Sheet L 831 R

6. Questions & Answers about HYgene Water Purification Process - Brochure H-174
7. General Ionics HYgene Water Purifier - Specification Sheet HYG-10-70
8. HYgene Water Purifiers - Industrial/Municipal Specification Sheet HYI-672
9. (a) HYgene shipping carton label - HYgene Water Purification Media
(b) HYgene Water Purifier label
10. Method for Determining Total Silver Content of HYgene
11. Public Health Service Drinking Water Standards Revised 1962
Pages 8, 52, 53 and 54
12. Standard Methods for the Examination of Water and Waste Water
by APHA, AWWA, WPCF - Pages 309 thru 316, 678 thru 683
13. "Basis for Choice of Hyla Silver Disinfecting System for Drinking Fountain, Home, and Small Institutional Supplies, and for Swimming Pool Waters" by Dr. Charles E. Renn of The Johns Hopkins University Note: The name of the product was changed from Hyla to HYgene in 1969.
14. "Results of Study to Determine the Comparative Bactericidal Efficiencies of Silver as Silver Nitrate and Silver Activated by the Hyla Process" by Dr. William E. Chesney of The Johns Hopkins University.
15. "Report on Bactericidal Effect of Hyla 603-KM at Varying Temperature Levels" by Dr. William E. Chesney of The Johns Hopkins University
16. "Performance Record of Experimental Hyla Treatment of Well Water Supply of G. Ward Barstow Residence, Bradshaw, Maryland" by Dr. William E. Chesney of The Johns Hopkins University
17. "Effects of Surface Blocking upon Activity of Hyla 603-KM: Methods of Study" by Dr. William E. Chesney of The Johns Hopkins University
18. NASA Tech Briefs No. B68-10555 and TSP71-10278
19. "Notes on Tolerance of Humans to Ingested Silver" by Dr. Charles E. Renn, The Johns Hopkins University
20. Addendum to A. Description of the Hyla Process
Question: Has Silver a toxic effect on the human organism?
by Dr. E. Hofer, Geneva, January 18/54

21. "Preliminary Report on the Installation of a Hyla Water Purification System - U.S. Navy Preventive Medicine Unit No. Two"
22. Four Years Bacteriological Ship's Report 1956-1960
23. "Silver Cleans up Polluted Water" - The Silver Institute Letter, Volume III, Number 7 July-August 1973
24. "The Story of Silver in Medicine" by Dr. Harry Margraf Gold & Silver Newsletter, September 1974
25. DODUCO letter of November 16, 1973 with report on experiences with a HYgene Water Purifier HY-45
26. Stage Coach Motel letter of August 8, 1971 with Bacteriological Reports from The Commonwealth of Pennsylvania, Department of Health on HYgene Water Purifier
27. United Engineers and Construction information on HYgene Water Purification System.
28. Fonderlac Country Club letter concerning HYgene system with Bacteriological Reports from County Health Department
29. NUS Corp., C. W. Rice Division Laboratory Report 5/28/74 on the Arnold Industries HYgene Water Purifier
30. NUS Corp., C. W. Rice Division Laboratory Report 6/6/74 on the Pure Water Maker Water Purifier manufactured by Water Purification Technology
31. NUS Corp., C. W. Rice Division Laboratory Report 6/19/74 on the Pure Water Maker Water Purifier manufactured by Water Purification Technology

In addition to the above enclosures, we would like to offer these comments with respect to requested information in the order asked in Chapter 1 - Food and Drug Administration, § 121.51 Petitions proposing regulations for food additives.

A.

1. Our Enclosure No. 1 describes the physical properties of HYgene including the chemical identity and composition as well as its biological properties and intended use which is for the purification of bacteriologically contaminated water.
2. The step by step method of manufacture of HYgene is in our Enclosure No. 2. (This is proprietary information of Ionics, Incorporated). Our quality control of the finished product is Enclosure No. 3 and also Enclosure No. 10. Enclosure No. 3 method is used on every HYgene lot manufactured. Enclosure No. 10 is a procedure periodically used by an outside laboratory.
3. Bacteriological analyses used in our quality control are performed by the SABRO Laboratory (Enclosure No. 5) which uses the membrane filter technique. This procedure is in accordance with Standard Methods for the Examination of Water and Wastewater published jointly by the APHA, AWWA, and WPCF. See Enclosure No. 12, Pages 678 thru 683.
4. Silver is determined in our laboratory by procedure found in Enclosure No. 4. In addition to this colorimetric procedure, we also periodically send samples to an outside laboratory for silver analysis by the Atomic Absorption (AA) method.

The AA method is very accurate in the range of 10 to 50 ppb and can be run by any reasonably well equipped lab. We have this AA equipment at our Watertown, Massachusetts lab. See Enclosure No. 12, Pages 309 thru 316.

5. The list of chemicals and quantities used in the manufacture of our HYgene product can be found on Page 5 of Enclosure No. 2. After undergoing chemical changes throughout the manufacturing procedure, the finished product contains:

Active Ingredient - Metallic Silver	1.05%
Inert Ingredient - Activated Carbon	98.95%
Total Ingredients	100.00%

A. continued

6. HYgene has an indefinite shelf life when stored in our shipping containers and in accordance with our labeling instructions (Enclosure No. 9) which states that it should be stored in closed container which excludes moisture and chemical fumes. Our shipping container is of heavy cardboard carton construction, lined with sealed, sanitary polyethylene bag.

B.

1. The HYgene media shipping carton label is Enclosure No. 9 (a) and the HYgene unit label is 9 (b). We are adding to these labels the active and inert ingredients with percentages as stated above under A-5.
2. The human tolerance limitation for silver in drinking water is 50 parts per billion (ppb) as indicated in Enclosure No. 11, Page 8 of the Public Health Service Drinking Water Standards. Also, in this same book, Pages 52, 53 and 54 discuss, a) studies of the metabolism of silver from intragastric intake in rats, b) a study of the toxicologic effects of silver added to drinking water of rats, and c) a study of the resorption of silver through human skin.

NASA Tech Brief 68-10555, Enclosure No. 18 states "Silver Ions in concentrations of 50 to 100 ppb which are nontoxic when ingested, have been recognized for many years as an effective bactericide.

C.

1. As water passes through a layer or bed of our HYgene product, silver is released into the effluent water under the standard limitations of 50 ppb. In addition to the silver being under these limitations, it is also in sufficient quantity to have the intended bacteriological effect on pathogenic bacteria. Laboratory testing in regard to this can be found in Enclosure Nos. 14, 15, 17, 29, 30 and 31. Actual field test data can be found in Enclosure Nos. 16, 21, 22, 25, 26 and 28.

Additionally, Ionics installed a 100,000 GPD HYgene potable water system (Enclosure No. 27) at The United Engineers and Constructors Jobsite of the Pennsylvania Power and Light Company, Martins Creek Steam Electric Station, Martins Creek, Pennsylvania, in September, 1971. This system is designed to produce potable water from Delaware River water for the approximately 1200 construction workers on site and has been in continuous operation since 1971, producing in excess of 32,000,000 gallons of potable water since startup. This installation was made and continues to operate under authority of the Pennsylvania Department of Health and Environmental Engineering.

D.

1. Methods used to determine the amount of silver in HYgene systems effluent are as discussed under A-4 of this letter. Consistent accurate results can be achieved by any properly equipped testing laboratory.

E.

1. Investigations with respect to the safety of the use of HYgene were conducted under the direction of Dr. Charles E. Renn of The Johns Hopkins University, Department of Sanitary Engineering and Water Resources. See Enclosure No. 19 regarding tolerance of humans to ingested silver in the range effected by the HYgene process. In this regard, also see comments from Dr. E. Hofer in Enclosure No. 20.

This is also answered by Enclosure No. 11.

F.

1. Tolerances and limitations of silver in drinking water are covered by Public Health Service Standard Drinking Water Standards. Enclosure No. 11.

G.

1. Not applicable

H.

1. Effluent from manufacturing process disposed to drain contains common chemicals as listed in Enclosure No. 2 in a dilute form.

H. continued

2. In the ultimate use as drinking water, there are no ill effects as indicated in Part B-2 of this letter concerning toxicity of silver. Water from the HYgene system effluent going to drain or waste is also harmless since it contains no more than 50 ppb silver.

Please also note Dr. Harry Margraf's article (Enclosure No. 24) in the Gold & Silver Newsletter, "The Story of Silver in Medicine". On Page 4, Dr. Margraf states, "Silver filters are used to transform polluted waste into drinking water. It's more effective and safer than chlorine, ozone or ultraviolet radiation." Also, he says, "I believe that in the not-to-distant future silver compounds will become the standard method for purifying the public water supply. Silver compounds will play an important role in pollution control."

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant



W. J. Polens
Vice President

WJP/no

Enclosure

STATEMENT OF OFFER TO PAY AND METHOD OF SUPPORT



SUBJECT: (Name of Pesticide Product) **HYgenetm**
(EPA Registration Number or File Symbol)
(Date of Application) **2/10/75**

1. I hereby offer to pay reasonable compensation to the extent provided under Section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and in accordance with the interim policy statement published in the Federal Register on November 19, 1973, for use of any test data, which had been submitted to the Environmental Protection Agency in connection with an application for the registration of a pesticide for the first time on or after October 21, 1972, and which may be used in support of the registration application for the subject pesticide. .

2. The method of support to be used in the review of this application is as follows: (list or check one only)

- ☐ a. ALL OF THE REQUIRED SUPPORTING DATA IS ATTACHED.
(Only the actual data submitted is to be used in the evaluation of this application.)
- ☐ b. ALL OF THE REQUIRED SUPPORTING DATA IS BEING SUBMITTED BY REFERENCE.
(Only the specific references submitted are to be used in the evaluation of this application. Any combination of data and references should be submitted as 2.b. with the data listed with the reference.)
- ☒ c. PROCEED ON THE BASIS OF ESTABLISHED USE PATTERNS.
(Any application for which the applicant desires the Agency to use any or all available information in addition to what is provided by the applicant must proceed under 2.c. Applications containing data for specific uses or references for part of the required information, but requiring additional information already on file with the Agency to be complete, must proceed under 2.c.)

(Signature of Applicant) *W. J. Polens*

(Name of Applicant) **W. J. Polens**

(Title of Applicant) **Vice President, Ionics, Inc.; P.O. Box 99; Bridgeville, Pa. 15017**

(This statement must be signed by an authorized representative of the applicant.)



BACTERIOSTATIC WATER FILTER MEDIA

Inhibits the growth of bacteria

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and chemical fumes.

EPA Reg. No. 35900-2

EPA Est. No. 35900 PA 01

ACTIVE INGREDIENT

METALLIC SILVER -----1.05% LOT NO. _____

INERT INGREDIENT

ACTIVATED CARBON -----98.95%

DIRECTIONS FOR USE:

NET CONTENTS _____ cu. ft.

Flow rate is not to exceed 15 GPM per cu. ft. of media. Bed depth must be at least twice the diameter.

DISPOSAL OF SPENT MEDIA: -----

Retain shipping carton and plastic liner for disposing of exhausted filter media with trash.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment

IONICS, INCORPORATED Routes 519 & 50, Bridgeville, Penna. 15017

TECHNICAL BULLETIN

IONICS, INCORPORATED - BRIDGEVILLE, PENNSYLVANIA

HYGENETM WATER PURIFICATION PROCESS DESCRIPTION OF MATERIAL AND DESIGN PRACTICE



I. DISINFECTION WITH SILVER

The use of silver in the disinfection of water supplies has long been recognized as an established technique. The principle of the HYgeneTM process is as follows. Silver ions absorbed on sponge silver metal is deposited on an inert carrier. Activated carbon of high surface area has been found to be an excellent carrier and it is the base of HYgeneTM. The silver is deposited in an oligodynamic or finely divided form in such a way that the solubility is limited to meter trace quantities. Therefore, contaminated water, contacting the silver impregnated carbon, will dissolve or release very minute quantities of silver in the range of 25 to 40 parts per billion. HYgeneTM is an effective disinfecting material against pathogenic intestinal organisms found in water. These include the germs that cause typhoid fever, dysentery, cholera, diarrhea and other such diseases. HYgeneTM will purify any water which is "bacteriologically acceptable for treatment" as defined in the United States Public Health Service Manual, RECOMMENDED WATER - SANITATION PRACTICE. In addition to its purifying qualities, HYgeneTM also filters the water and removes taste, odor and color from it.

II. HYGENETM RESEARCH

A major part of research and development investigation on the behavior of this media was carried out at The Johns Hopkins University Department of Sanitary Engineering under the direction of Dr. Charles E. Renn. All data included herein can be verified by accomplishments of this research program.

III. PHYSICAL PROPERTIES

The physical characteristics of HYgeneTM are comparable to those of activated carbon substrate upon which a silver salt of complex chemical structure coating is deposited. Addition of silver to the mass does not measurably alter the density of the parent carbon. The physical absorption capacity of the carbon is decreased not more than 2% by the presence of silver.

IV. DESIGN PRACTICE

All HYgeneTM installations made under the supervision of Ionics, Inc. have had a minimum bed contact time of one minute. Performance data has shown this to be adequate. The void space of the bed has been determined to be 40% and is used in all calculations. Under normal or average operating conditions, HYgeneTM material can be expected to treat 750,000 gallons of raw water per cubic foot. Equipment design is predicted on flow rate of 3 gallons per minute per cubic foot of material with the height of the filter bed at least twice the diameter of the filter. Installations are usually rated to give a minimum bed life of two years. To provide maximum residual kill, a storage reservoir following the HYgeneTM contact bed is recommended where bacteria count of water is excessively high or where demand flow rates are beyond limits. Removal of protective suspended solids is necessary for

IV. DESIGN PRACTICE (cont'd)

reliable chemical disinfection by any known agent. For optimum performance and long life of HYgene™ material, the removal of all possible solids prior to the contact bed is therefore desirable. Turbid waters may be clarified by settling, coagulation and settling or by fine filtration. Naturally clarified sources may require no pretreatment, though their inclusion is recommended to insure removal of cysts and larger waterborne intestinal parasites.

V. FIELD CONTROL

A. Bacteriological Test Kit

For an expedient method of measuring the bacteria content of the effluent supply, Ionics manufactures and markets the SABRO Portable Laboratory for bacteriological analysis of water. This unit was developed at The Johns Hopkins University by Dr. Charles E. Renn under a SABRO Fellowship Program. For further information on SABRO, contact Ionics, Incorporated at Bridgeville, Pennsylvania.

B. Silver Test Kit

To determine the silver concentration of treated water, Ionics recommends the use of LaMotte Chemical Company's Low Range Silver Test Kit. This unit is available from Ionics or LaMotte Chemical Company in Chestertown, Maryland.

VI. LABORATORY FACILITIES

Ionics laboratory equipment and technicians are available for complete chemical and bacteriological analysis. Samples of suspicious or problem

VI. LABORATORY FACILITIES (cont'd)

waters as well as treated water samples for quality control check may be sent to our laboratory for a complete analysis. Sampling bottles and recommended technique for collection of water samples are available at Ionics.

VII. RAW WATER CONDITIONS

For reliable operation of the HYgene™ system, the following conditions are necessary:

- A. Chlorides: 500 ppm maximum
- B. Sulfates: 2,000 ppm maximum
- C. Iron: 0.2 ppm maximum. Most raw waters high in iron content can be pretreated for its removal before HYgene™.
- D. Hydrogen Sulfide: Sulfide may limit the life of HYgene™ and its removal is therefore recommended before HYgene™ treatment.
- E. Color: 20 maximum. Color is used here to indicate high concentrations of extracted organic matter in water. If color exceeds this value, samples should be performance tested to determine the necessary equipment design required.
- F. pH: 5.0 to 8.5
- G. Temperature: 40° F to 85° F

VIII. COMMERCIAL INFORMATION

Mesh Size: 12 x 30 U.S. Sieve Series

Weight: 30 lbs. net per cubic foot

Packaging: 1 cu.ft. Fiber Drum or 200 lbs. (6.67 cu.ft.) Fiber Drum

Shipping Point: Bridgeville, Pennsylvania

SUBMISSION REVIEW RECORD				REGISTRATION NUMBER <i>PA 2</i>		SUBMISSION CODE	DATE RECEIVED		
ACTION TYPE				COMPANY NO.	PRODUCT NO.		YEAR	MONTH	DAY
G				359100	-00000E		75	02	27
CODE				PRODUCT MANAGER		CODE	PROJECTED RETURN		
						33	YEAR	MONTH	DAY
NEW CHEMICAL		NEW MIXTURE		SIGNIFICANT NEW USE		PETITION NUMBER		OUTGOING DATE	
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		545079		YEAR MONTH DAY	
SIGNIFICANT NEW USE F.R. NUMBER		F.R. PUBLICATION DATE		DATE EXCLUSIVE F.R. NUMBER		F.R. PUBLICATION DATE		3 CID PUBLICATION REQ	
		YEAR MONTH DAY		2C		YEAR MONTH DAY		<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
		015				75 03 24			
REV SEQ	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER		COMMENT CODE	DATE REVIEW COMPLETED		
	A	REVIEWABILITY TEAM	JAS	<i>John A. Shaughey</i>		TAL	75	03	04
	B	INSECTICIDE EFFICACY							
	C	HERBICIDE EFFICACY							
	D	FUNGICIDE EFFICACY							
	E	RODENTICIDE EFFICACY							
	F	DISINFECTANT EFFICACY		<i>R. J. R. Young</i>		OB	75	07	07
	G	RESIDUE CHEMISTRY							
	H	ENVIRONMENTAL CHEMISTRY							
	I	HUMAN SAFETY		<i>R. J. R. Young</i>		OB	75	07	22
	J	ENVIRONMENTAL SAFETY							
	K	INTERAGENCY REFERRAL							
	L	COST-BENEFIT REVIEW							
	M	PUBLIC COMMENTS REVIEW							
	N	PRODUCT MANAGER TEAM		<i>R. G. Douglas</i>		OB	75	07	23
	O	PRODUCT MANAGER							
	P	PRODUCT BRANCH CHIEF							
	Q	SCIENCE PEER REVIEW							
	R	REGISTRATION OFFICER							
	S	SCIENCE OFFICER							
	T	DIVISION DIRECTOR							
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE			RESPONSE CODE		
<i>LABEL PULLED (3CID)</i>				<i>Objection Ldr.</i>			<i>A-5</i>		
MAR 07 1975									

Public Health Service
Drinking Water Standards

Revised 1962



U.S. DEPARTMENT OF HEALTH, EDUCATION,
AND WELFARE

PUBLIC HEALTH SERVICE

Washington 25, D.C.

5.22 The presence of the following substances in excess of the concentrations listed shall constitute grounds for rejection of the supply:

Substance	Concentration in mg/l
Arsenic (As) -----	0.03
Barium (Ba) -----	1.0
Cadmium (Cd) -----	0.01
Chromium (Hexavalent) (Cr ⁺⁺) -----	0.05
Cyanide (CN) -----	0.2
Fluoride (F) -----	(See 5.23)
Lead (Pb) -----	0.05
Selenium (Se) -----	0.01
✓ Silver (Ag) -----	0.05

5.23 *Fluoride*.—When fluoride is naturally present in drinking water, the concentration should not average more than the appropriate upper limit in Table I. Presence of fluoride in average concentrations greater than two times the optimum values in Table I shall constitute grounds for rejection of the supply.

Where fluoridation (supplementation of fluoride in drinking water) is practiced, the average fluoride concentration shall be kept within the upper and lower control limits in Table I.

TABLE I.

Annual average of maximum daily air temperatures ¹	Recommended control limits— Fluoride concentrations in mg/l		
	Lower	Optimum	Upper
40.0-53.7 -----	0.9	1.2	1.7
53.8-59.3 -----	0.8	1.1	1.6
59.4-63.9 -----	0.8	1.0	1.5
64.0-70.8 -----	0.7	0.9	1.4
70.9-79.2 -----	0.5	0.8	1.0
79.3-90.5 -----	0.6	0.7	0.8

¹ Based on temperature data obtained for a minimum of five years.

In addition to the sampling required by paragraph 5.1 above, fluoridated and defluoridated supplies shall be sampled with sufficient frequency to determine that the desired fluoride concentration is maintained.

6. RADIOACTIVITY

6.1 Sampling.

6.11 The frequency of sampling and analysis for radioactivity shall be determined by the Reporting Agency and the Certifying Authority after consideration of the likelihood of significant amounts being present. Where concentrations of Ra²²⁶ or Sr⁹⁰ may vary considerably, quarterly samples composited over a period of three months are recommended. Samples for determina-

SELENIUM

The presence of selenium in water has heretofore been a matter of regional importance (1). The fact that it is now recognized as being toxic to both man and animals makes it essential that limits be set for all water intended for human consumption.

Selenium is known to produce "alkali disease" in cattle, and its effects, like those of arsenic, may be permanent (1,2). Recent reports indicate also that selenium may increase the incidence of dental caries in man (3). Of greater importance in limiting the concentration of selenium is its potential carcinogenicity (4). Rats fed a diet containing varying concentrations of selenium (3 to 40 mg/l) showed toxic effects at all levels, the outstanding pathologic lesion being hepatic cell tumors.

From very limited information (5) concentrations of selenium in water considered safe for man have been found toxic for fish.

In view of the potential seriousness of above reported effects, it is recommended that the limits for selenium be lowered from its present value of 0.05 mg/l to 0.01 mg/l and concentrations in excess of this lower value be used as grounds for rejection of the supply.

LITERATURE CITATIONS

1. Dudley, H. C. Toxicology of selenium: I. A study of the distribution of selenium in acute and chronic cases of selenium poisoning. *Am. J. Hyg.* 23: pp. 169-186 (1936).
2. Drill, V. A. Pharmacology in Medicine. Ed. 2, New York, N.Y., McGraw-Hill, 1958, pp. 794-795.
3. Hadjilarkos, D. M., and Bonhorst, C. W. The trace element selenium and its influence on dental caries susceptibility. *J. Pediat.* 52: pp. 274-278 (1958).
4. Fitzhugh, O. G., Nelson, A. A., and Bliss, E. I. The chronic oral toxicity of selenium. *J. Pharm. Exp. Ther.* 80: pp. 283-299 (1944).
5. Ellis, M. M. Pollution and aquatic life. *Am. Wildlife* 26: pp. 38, 45-46 (1937).

SILVER

✓ The need to set a water standard for silver (Ag) arises from its intentional addition to waters for disinfection. The chief effect of silver in the body is cosmetic, which consists of a permanent blue-grey discoloration of the skin, eyes, and mucous membranes which is as unsightly and disturbing to the observer as to the victim. The amount of colloidal silver required to produce this condition (argyria, argyrosis), and which would serve as a basis of determining the water standard, is not known, but the amount of silver from injected Ag-arsphenamine, which produces argyria is precisely known. This value is any amount greater than 1 gram of silver, 8g Ag-arsphenamine in an adult (1, 2).

From a review (2) of more than 200 cases of argyria, the following additional facts were derived. Most common salts of silver produce argyria when taken by mouth or by injection. There is a long-delayed appearance of discoloration. No case has been uncovered that has resulted from an idiosyncrasy to silver. There was, however, considerable variability in predisposition to argyria; the cause of this is unknown but individuals concurrently receiving bismuth medication developed argyria more readily. Although there is no evidence that gradual deposition of silver in the body produces any significant alteration in physiologic function, authorities are of the opinion that occasional mild systemic effects from silver may have been overshadowed by the striking external changes. In this connection, there is a report (3) of implanted silver amalgams resulting in localized argyria restricted to the elastic fibers and capillaries. The histopathologic reaction resembled a blue nevus simulating a neoplasm with filamentous structures and globular masses. Silver affinity for elastic fibers had been noted a half-century earlier (5).

A study (5) of the metabolism of silver from intragastric intake in the rat using radio-silver in carrier-free tracer amounts showed absorption to be less than 0.1–0.2 percent of the silver administered; but this evidence is inconclusive because of the rapid elimination of silver when given in carrier-free amounts. Further study indicated, however, that silver is primarily excreted by the liver. This would be particularly true if the silver is in colloidal form. Silver in the body is transported chiefly by the blood stream in which the plasma proteins and the red cells carry practically all of it in extremely labile combinations. The half-time of small amounts of silver in the blood stream of the rat was about 1 hour. A later report (6), using the spectrographic method on normal human blood, showed silver unmistakably in the red blood cell and questionably in the red cell ghosts and in the plasma. Once silver is fixed in the tissues, however, negligible excretion occurs in the urine (7).

A study (8) of the toxicologic effects of silver added to drinking water of rats at concentrations up to 1,000 $\mu\text{g}/\text{l}$ (nature of the silver salt unstated) showed pathologic changes in kidneys, liver, and spleen at 400, 700, and 1,000 $\mu\text{g}/\text{l}$.

A study (9) of the resorption of silver through human skin using radio-silver Ag^{111} has shown none passing the dermal barrier from either solution (2 percent AgNO_3) or ointment, within limits of experimental error (± 2 percent). This would indicate no significant addition of silver to the body from bathing waters treated with silver.

Great uncertainty, however, currently surrounds any evaluation of the amount of silver introduced into the body when silver-treated

water is used for culinary purposes. It is reasonable to assume that vegetables belonging to the family Brassicaceae, such as cabbage, turnip, cauliflower, and onion, would combine with residual silver in the cooking water. The silver content of several liters of water could thus be ingested.

Despite these uncertainties and the present lack of appropriate drinking water studies, it is possible to derive a tentative drinking water standard for silver by using silver deposited in excess of 1g in the integument of the body as an end point that must not be exceeded. Assuming that all silver ingested is deposited in the integument, it is readily calculated that 10 ug/1 could be ingested for a lifetime before 1g silver is obtained from 2 liters water intake per day; 50 ug/1 silver could be ingested approximately 27 years without exceeding silver deposition of 1g.

Because of the evidence (7) that silver, once absorbed, is held indefinitely in tissues, particularly the skin, without evident loss through usual channels of elimination or reduction by transmigration to other body sites; and because of the probable increased absorbability of silver as silver-bound sulfur components of food cooked in silver-treated waters, the intake for which absorption was reported in 1940 to amount to 60-80 ug per day (10); and because of the above calculation, a concentration in excess of 50 ug/1 is grounds for rejection of the supply.

LITERATURE CITATIONS

1. Hill, W. B., and Pillsbury, D. M. *Argyria*. The pharmacology of silver. Baltimore, Md., Williams & Wilkins, 1939, 172 pp.
2. Ibid., *Argyria Investigation—Toxicologic Properties of Silver*, Am. Silver Producers Res. Proj. Report, Appendix II (1957).
3. Bell, C. D., Cookey, D. B., and Nickel, W. R. Amalgam tattoo-localized argyria. *A.M.A. Arch. Derm. Syph.* 60: pp. 523-525 (1952).
4. Joseph, M., and Van Deventer, J. B., *Atlas of Cutaneous Morbid Histology*. W. T. Kilner & Co., Chicago, 1906.
5. Scott, K. G., and Hamilton, J. G. The metabolism of silver in the rat with radiosilver used as indicator. *U. of Cal. Publ. in Pharm.* 2: pp. 241-262 (1950).
6. Wyckoff, R. O., and Hunter, F. R. Spectrographic analysis of human blood. *Arch. Biochem.* 63: pp. 454-460 (1958).
7. Aub, J. C., and Fairbairn, L. T. Excretion of silver in urine. *J.A.M.A.* 118: p. 310 (1942).
8. Just, J., and Szatmari, A. Germicidal properties of silver in water. *J. Am. Water Works A.* 29: pp. 492-506, April 1938.
9. Norgaard, O. Investigations with Radio Ag^{110} into the resorption of silver through human skin. *Acta Dermato-venereol.* 34: pp. 415-419 (1954).
10. Kehoe, R. A., Cholak, J., and Story, R. V. Manganese, lead, tin, copper and silver in normal biological material. *J. Nutr.* 20: pp. 85-98 (1940).

Enclosure
BRIDGEVILLE, PENNSYLVANIA 15017 TELEPHONE 334-1111

June 25, 1971

United Engineers and Constructors
P. O. Box 231R
Martins Creek, Pennsylvania 18063

Attention: Mr. William Homeyer
Piping Superintendent

Ref: HYgene® Water Purification System
for PP&L Co., Martins Creek
Steam Plant

Gentlemen:

On June 24, 1971, a meeting was held in the Reading, Pennsylvania district offices of the Pennsylvania Dept. of Health and Environmental Engineering to discuss the HYgene® water purification system proposed for the above referenced installation.

Attending:

Messrs Kuder, Parks, Becker and Darrall, Pennsylvania Dept.
of Health & Environmental Engineering, Reading

Mr. Paul Zimmerman, Department of Environmental Resources,
Harrisburg

Messrs Polens and Schmidt, Ionics, Inc., Bridgeville, Pa.

The water system for the construction site will be classified as a "semi-public" system as opposed to a "public" system. This is a very important differentiation since a "public" supply would require submission of an application for Public Water Supply Form H711.513 to the State for approval. Mr. Kuder

June 24, 1953

1. 1. 1. 1.

With this stipulation met, United Engineers should submit plans for the complete water treatment and distribution system to:

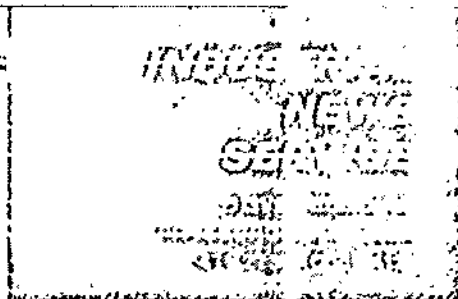
Mr. Becker estimates, that if the submitted information is complete, he will require one week to ten days for approval. The State will monitor system performance after startup, by testing both silver residual and coliform count. We have furnished a Hach low range silver field test kit to Mr. Becker for this purpose. In addition we have furnished a copy of our proposal to Mr. Becker and a binder containing complete specifications and documentation on HYgene® for their files.

Very truly yours,

R. C. Hunt

RCS:b1f

ed for Ionics, Incorporated
Box 99
Bridgeville, Pa. 15017
ore information contact A. E. Daniell
Phone: 412/343-1040



SILVER DISINFECTANT SYSTEM
EFFICIENTLY PURIFIES WELL WATER
ODOR-FREE AT 100,000 GALLONS/DAY

BRIDGEVILLE, PA. -- Ionics, Incorporated completed a contract from United Engineers & Constructors for a HYgene water purification plant that will turn well water into potable drinking water in excess of 100,000 gallons per day. The installation of the treatment facility is located in Martins Creek, Pennsylvania where United Engineers is constructing a new power plant for Pennsylvania Power & Light Company.

The HYgene water purifier is a silver disinfectant system that will purify any water which is bacteriologically acceptable for treatment as defined by the United States Department of Health Service Manual. It is particularly effective as a disinfecting material against pathogenic intestinal organisms found in water, including germs that cause typhoid fever, dysentery, cholera or diarrhea.

In addition to its purifying qualities, HYgene units filter the water and remove objectionable taste, odor and color without the use of chlorine or other chemicals. The taste problem of chlorinated water has been an increasing concern for field superintendents in the construction and related industries as job-site working crews object more and more strenuously to the

unpleasant taste of chemically treated water.

The silver purification system was chosen because it is also simple to operate and economical to maintain. The effluent is unaffected by exposure to light or increased temperature. A periodic backwash keeps the system functioning. Ionics' Sabro^(R) test kit, employing the membrane filter technique, is used to provide an accurate and rapid bacteriological analysis of the water.

Contact Ionics, Incorporated, Bridgeville, Pa. 15017 for more information on HYgene silver disinfectant systems that are available in commercial sizes for resorts, restaurants, real estate developments, service stations, oil and mining camps and ranches.

#

#

#

Box 145
Mt. Bethel Pa. 18343

February 10, 1975

To Whom It May Concern:

In the spring of 1971 I was instrumental in the decision of our company to use a General Ionics Water Treatment Plant for our construction project at Martins Creek Pennsylvania.

We anticipated a total force of over 1200 people at peak use with consumption rates of over 200 G.P.M. during peak hours.

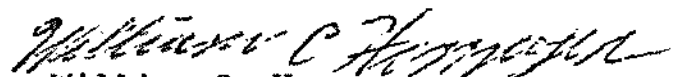
Our water was well water, known to be contaminated beyond allowable limits, but of low turbidity. A silver impregnated Carbon Filter was used. Fully automated low maintenance operation was a requirement that had to be met.

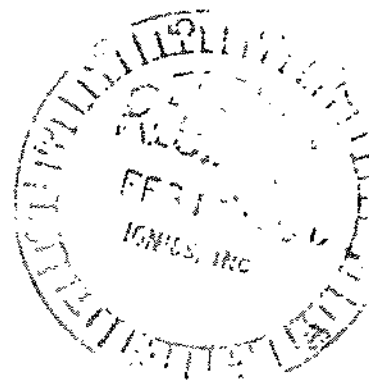
Daily testing for bacteria was conducted during the first few months of operation as well as testing for silver content. Later these tests were reduced in frequency. We are pleased to state that at no time was any evidence of bacteria found.

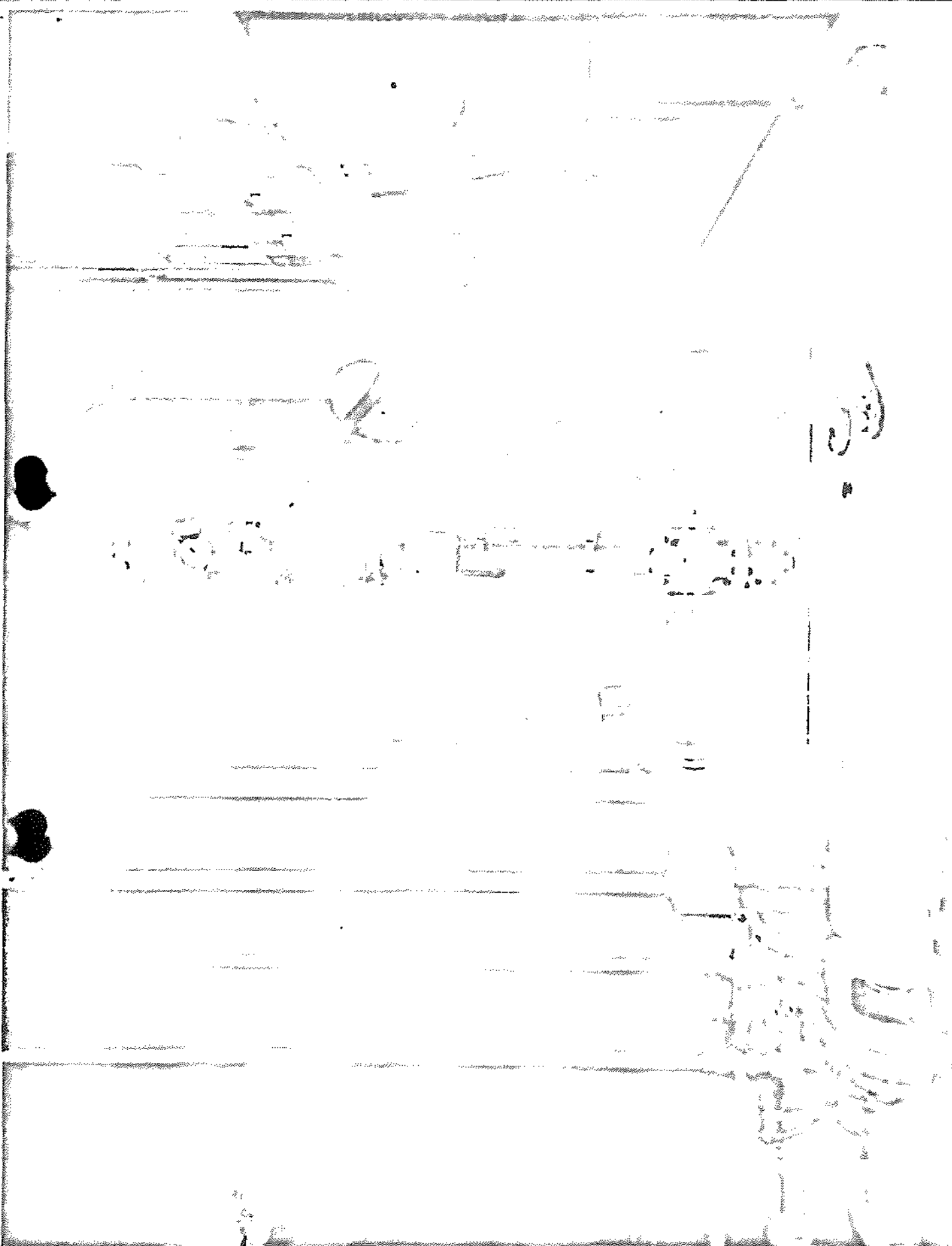
This plant has more then met all of my anticipations and I am in the process of recommending its use on future sites.

The plant was inspected by the state water board and met with its approval.

Respectfully.


William C. Homeyer
Piping Supt.
United Engineers & Constr.





PJ

PRODUCT DATA SUMMARY

TRANS - ACTION	DATE MM-YY	TOXICITY CODE	PRODUCT CODE	MANAGER NAME	REGISTRATION NUMBER
	10-75	3	33	J. BANKS	035900-00002
-----	-----	-----	-----		

HYGENE

TYPE CODE	T Y P E
24	BACTERIOSTAT
-----	-----

FORM CODE	F O R M
67	GRANULAR PELLETTED OR CRYSTAL PRODUCT
-----	-----

CFEM CODE	PERCENT	C H E M I C A L
072501	1.0500	SILVER
-----	-----	-----
-----	-----	-----

Confidential Statement of Formula may be entitled to confidential treatment

INSTRUCTIONS

NOTE: Use a separate form for each Formulation.

Applicant - keep the second copy for your files and forward the original to EPA or follow the instructions in "C" below.

- A. The complete chemical composition of each pesticide must be known so it can be evaluated for registration under the Federal Insecticide, Fungicide and Rodenticide Act. This information is also necessary to determine the status of ingredients, both active and inert, under the Pesticide Chemicals Amendment to the Federal Food, Drug and Cosmetic Act.
- B. This form is designed for reporting the ingredients used in the formulation of a pesticide. Its use will speed the review. It must be completed and submitted with each EPA Form 8570-1, Application For New Registration Of A Pesticide, or with each EPA Form 8570-2, Application For Amended Registration Of A Pesticide, if revision involves a formula change, or with each EPA Form 8570-3, Application For Renewal Registration Of A Pesticide.
- C. If the complete chemical composition of formulated ingredients, either active or inert, used in this product's formulation is not known to you, send a separate set of these forms for each ingredient to your Basic Supplier. When you do this, it is important that you first fill in items 2 thru 8 so that we may positively identify the supplier's product with your pesticide. The Basic Supplier is then requested to complete items 1, and 9 thru 15, and submit the form to this Division. This statement is treated confidentially. It cannot be used to support a customer's (formulator's) application for subsequent registration without written authorization from the Basic Supplier.

ITEM No.

1. If more than 1 page is required, number them "1 of 2", "1 of 3", etc.
2. Enter the same date as the Application.
3. Read instruction "B" above.
4. Enter the name and address of your firm.
5. Enter the product name of this pesticide as it will appear on the finished label.
6. Enter the EPA Registration Number or File Symbol if known.
7. Complete if required by instruction "C" above.
8. Complete if required by instruction "C" above.
9. Completed only by Basic Supplier.
10. Completed only by Basic Supplier.
11. List first all active ingredients then the inert ingredients each in the exact order as they will appear on the finished label. When a formulated product is listed in the formula, name its basic manufacturer and give its EPA Registration No., if known, in parenthesis following the name of the product. (Also see instruction "C" above.) The trade name and manufacturer of surfactants and other adjuvants (dyes, emulsifiers, solvents, perfumes) must be listed. The complete chemical composition of emulsifiers and surfactants must be listed. Enclose the manufacturer's name in parenthesis following the product listed by trade name. (Also see instruction "C" above.) If a dye or other coloring is used, state the color.
12. Enter the percentage by weight of each active and inert ingredient beside the ingredient to which it applies. The percentages by weight for the active ingredients must agree with those appearing in the ingredient statement on the label. The sum of all percentages listed must equal 100 percent.
13. Self explanatory.
14. Self explanatory.
15. Self explanatory.

PRODUCT LABEL CODED INFORMATION (New)
(Use this form to enter New Products)

I- ADD ONLY

1. CARD CODE <div>1</div> (Col. 1)	2. ACTION CODE <div>A</div> (Col. 2)	3. MANUFACTURER <div>0359000000002</div> (Col. 3-8)	4. PRODUCT <div>0359000000002</div> (Col. 9-13)
5. DATE <div>(MO) (YR)</div> (Col. 14-17)	6. TYPE OF PESTICIDE <div></div> (Col. 18-33)	7. FORM <div>33</div> (Col. 36-39)	8. CAT TOX <div></div> (Col. 40)

II

1. CARD CODE <div>2</div> (Col. 1)	2. ACTION CODE <div>1</div> (Col. 2)	3. MANUFACTURER <div>0359000000002</div> (Col. 3-8)	4. PRODUCT <div>0359000000002</div> (Col. 9-13)	(Same as Card 1)
--	--	---	---	------------------

5., 6. INGREDIENTS AND PERCENTAGES

1 <div>072501</div> 14 19	2 <div>010500</div> 20 % 25	3 <div></div> 26 31	4 <div></div> 32 % 37	5 <div></div> 38 43	6 <div></div> 44 % 49
---------------------------------	-----------------------------------	---------------------------	-----------------------------	---------------------------	-----------------------------

1ST CARD

7 <div></div> 50 55	8 <div></div> 56 % 61	9 <div></div> 62 67	10 <div></div> 68 % 73
---------------------------	-----------------------------	---------------------------	------------------------------

5., 6. INGREDIENTS AND PERCENTAGES

1 <div></div> 14 19	2 <div></div> 20 % 25	3 <div></div> 26 31	4 <div></div> 32 % 37	5 <div></div> 38 43	6 <div></div> 44 % 49
---------------------------	-----------------------------	---------------------------	-----------------------------	---------------------------	-----------------------------

2ND CARD

7 <div></div> 50 55	8 <div></div> 56 % 61	9 <div></div> 62 67	10 <div></div> 68 % 73
---------------------------	-----------------------------	---------------------------	------------------------------

5., 6. INGREDIENTS AND PERCENTAGES

1 <div></div> 14 19	2 <div></div> 20 % 25	3 <div></div> 26 31	4 <div></div> 32 % 37	5 <div></div> 38 43	6 <div></div> 44 % 49
---------------------------	-----------------------------	---------------------------	-----------------------------	---------------------------	-----------------------------

3RD CARD

7 <div></div> 50 55	8 <div></div> 56 % 61	9 <div></div> 62 67	10 <div></div> 68 % 73
---------------------------	-----------------------------	---------------------------	------------------------------

II

1. CARD CODE

2
(Col. 1)

2. ACTION CODE

U
(Col. 2)

3. MANUFACTURER

4. PRODUCT

0359000002
(Col. 3-8) (Col. 9-13)

(Same as Card 1)

5. USE CATEGORIES

1ST CARD

1
14 18

2
19 23

3
28 32

4
29 33

5
34 38

6
39 43

7
44 48

8
49 53

9
54 58

10
59 63

11
64 68

12
69 73

13
74 78

5. USE CATEGORIES

2ND CARD

1
14 18

2
19 23

3
28 32

4
29 33

5
34 38

6
39 43

7
44 48

8
49 53

9
54 58

10
59 63

11
64 68

12
69 73

13
74 78

5. USE CATEGORIES

3RD CARD

1
18 22

2
19 23

3
28 32

4
29 33

5
34 38

6
39 43

7
44 48

8
49 53

9
54 58

10
59 63

11
64 68

12
69 73

13
74 78

EPA H₂ Form T-46 (10-74) (Reverse)



IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

February 19, 1976

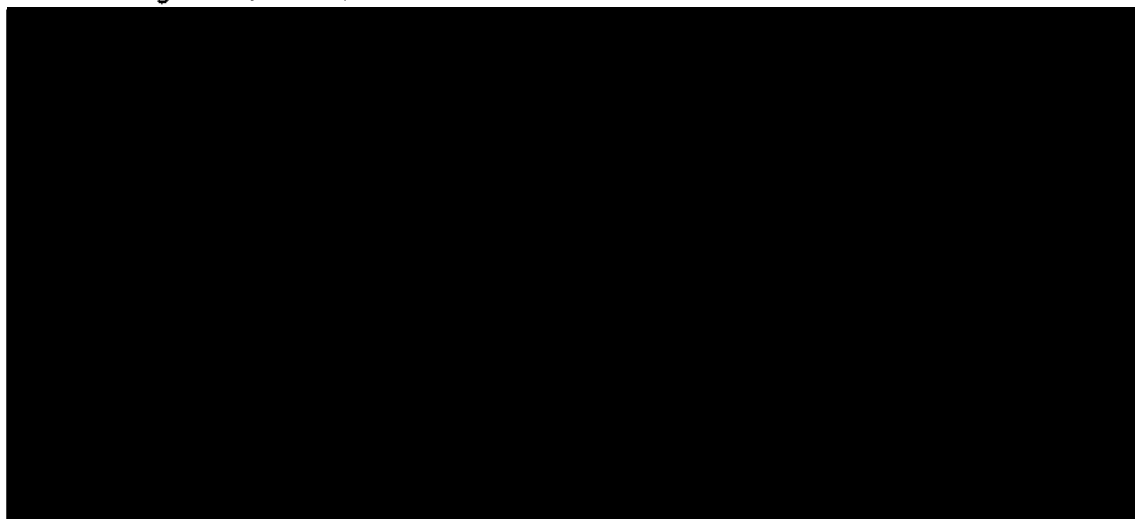
Mr. James H. Banks, Product Manager (33)
Disinfectants Branch
Registration Division (WH-567)
United States Environmental Protection Agency
401 M Street S.W.
Washington, D. C. 20460

Subject: HYgene
EPA Reg. No. 35900-2
Your Letter of Jan. 20, 1976

Dear Mr. Banks:

This is in reply to your letter dated January 20, 1976 in reference to general chemistry data for HYgene.

- A.1 You are correct in stating that the active ingredient is essentially 100% metallic silver with only traces of impurities. OK
- A.2 Correct. Manufacturing process is the same as in Petition 5H5079. OK
- A.3 Purity of ingredients used in the manufacturing process of HYgene are as follows: OK



92427

88843

Quality control process information may be entitled to confidential treatment

SUBMISSION REVIEW RECORD			1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED		
3. 3CID PUBLICATION NECESSARY <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			4. PETITION NO.					MO	DAY	YR
6. METHOD OF SUPPORT <input type="checkbox"/> 2A <input type="checkbox"/> 2B <input type="checkbox"/> 2C			7. PRODUCT MANAGER <i>Banks</i>				NO.	MO	DAY	YR
9. DATE PULLED		10. DATE PUBLISHED		11. ACTION TYPE <i>Resubmission without data</i>			CODE	12. OUTGOING DATE		
								MO	DAY	YR
REV. SEC.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER			COM-MENT CODE	DATE REVIEW COMPLETED		
	A	REVIEWABILITY TEAM						MO	DAY	YR
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW								
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW								
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW								
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW	<i>RGD</i>	<i>R. Douglas</i>			<i>DB</i>	<i>12</i>	<i>22</i>	<i>75</i>
	F	PRODUCT MANAGER								
	G	INTERAGENCY REFERRAL								
	H	COST-BENEFIT REVIEW								
	I	PUBLIC COMMENTS REVIEW								
	J	EEE BRANCH INSECTICIDE EFFICACY								
	K	EEE BRANCH HERBICIDE EFFICACY								
	L	EEE BRANCH FUNGICIDE EFFICACY								
	M	EEE BRANCH RODENTICIDE EFFICACY								
	N	EEE BRANCH DISINFECTANT EFFICACY	<i>DMP</i>	<i>D. Portner</i>						
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY								
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY								
	Q	TOXICOLOGY BRANCH HUMAN SAFETY								
	R	EEE BRANCH ENVIRONMENTAL SAFETY								
	S									
	T									
PRODUCT MANAGER SIGNATURE <i>James H. Banks</i>				TYPE OF RESPONSE <i>Reg. Tr.</i>				CODE		



IONICS
IONICS, INCORPORATED

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A.C. 412 343-1040 TWX 5106973299

October 14, 1975

AIRMAIL - SPECIAL DELIVERY - CERTIFIED MAIL - RETURN RECEIPT REQUESTED - ADDRESS ONLY

United States Environmental Protection Agency
Disinfectants Branch, Room 321
Registration Division (WH-567)
OPP - EPA
401 M. Street, S.W.
Washington, D.C. 20640

Attention: Mr. James H. Banks - PM 33

Subject: HYGENE
Ionics File Symbol 35900-E
Your letter dated October 9, 1975

Dear Mr. Banks:

Five finished labels for the above HYgene product are enclosed. On this label, we have made the following changes as requested in your letter dated October 9, 1975:

- 1) We have changed "Self-sanitizing" to read "Bacteriostatic".
- 2) We have changed the claim "Prevent the growth of bacteria" to read "Inhibits the growth of bacteria".
- 3) We have deleted "as a sanitizer".
- 4) We have corrected the typographical error in the spelling of silver.
- 5) In your letter under paragraph 5, you ask us to provide the necessary calculations to verify the flow rate recommended on the label is comparable to the flow rate used in these laboratory experimentation studies.

You may use the following equations to convert the 500 ml/minute and this will show that this is the same as 15 gallons per minute. The equation is as follows:

500 ml flow through column of 250 cc HYgene mineral is directly proportional to 15 gallons per minute per cubic foot of HYgene as follows:

- a) $500 \text{ ml/min.} = 0.132 \text{ gal./min.}$
- b) $250 \text{ cc HYgene} = 0.008828 \text{ cubic foot}$
- c) $0.132 \text{ gal./min.} / 0.008828 \text{ cubic foot} = 15 \text{ gals. per minute per one cubic foot.}$

Attention: Mr. James H. Banks - PM 33

Page 2

- 6) We have no collateral literature or technical bulletins or brochures that are being distributed with this product at present.

We have enclosed a copy of a letter that is being sent to all of our customers. If any literature or collateral material is developed to be sent with the product, we will send this to you for your approval.

In your letter dated October 9, 1975 under paragraph "D" 1, 2, 3, and 4 - you asked for additional information required to substantiate the bacteriostatic claim for the filter media.

- 1) Attached please find a letter from Ms. Linda Deans, Manager of Analytical Services for NUS Corporation who did the testing. In this letter Ms. Deans gives the concentration of the artificially contaminated water (inoculum) at the end of the test to ascertain the degree of natural "dieoff".
- 2) The neutralizing solution used contained 5% sodium thioglycollate and 7.3% sodium thiosulfate. One milliliter of this sterile neutralizing solution was added to sterile sample bottles in which 100 milliliters samples were collected for bacteriological testing.
- 3) Attached is a copy of our report "EVALUATION OF HYGENE PRODUCT MEDIA FOR EPA REGISTRATION". This was originally sent to you on September 3, 1975. Please note on page one under CHEMICAL, there is a listing of the production lots used for testing. Three of these lots are as follows:

Lot No. 05125, Lot No. 04075, Lot No. 03105

On page three of this report under BACTERIOLOGICAL, we list the three lot numbers used for bacteriological testing.

Lot No. 05125, Lot No. 04075, Lot No. 03105

Please note that these are both from the same lot numbers that we used in the chemical testing.

I refer you to the last paragraph on page two which states "Flow was discontinued to all three columns for a period of eighteen (18) hours." These samples were then acidified and sent to NUS Corporation with the suffix "C" and tested by atomic absorption for silver concentration. This included lot numbers 05125, 04075, and 03105. They were identified then as lot numbers 05125C, 04075C, 03105C. Attached to the above reference report is the NUS Corporation Atomic Absorption Test Report on the silver by lot numbers. None of the three lots went over the 50 ppb after an eighteen hour holding period. This conclusively proves that from these lots even sitting eighteen hours, we did not exceed 50 ppb. These are the lots that we used for the bacteriological tests.

Record Number 43421
Reference Number 2
Input Date 7-21-81

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

1 File Symbol/Reg.No. 35900-2 **2** PM 31 **3** Action Code 300

5. Intrastate Call-in ☐ (Y) Yes
☒ (N) No

7. Child-resistant Packaging:
☐ (Y) Yes ☐ (N) No

8. Registration Type:
☐ (1) Conditional ☐ (2) Unconditional

9. Proposed Classification:
☐ (R) Restricted
☐ (G) General

10. Final Classification:
☐ (R) Restricted ☐ (N) Not Classified
☐ (G) General

11 Date on Application:

MO	16	DAY	12	YR	81
----	----	-----	----	----	----

12 EPA Received Date:

MO	16	DAY	16	YR	81
----	----	-----	----	----	----

13 Date Received by PM.

MO	16	DAY	17	YR	81
----	----	-----	----	----	----

20. Method of Support:

21. Certification Statement:

☐ (1) Cite-All ☐ (4) Not Applicable ☐ (1) Yes ☐ (3) Not Applicable
☐ (2) Alternate ☒ (5) Not Submitted ☒ (2) Not Submitted
☐ (3) Combined

24 Reviews Requested:

10- RD
PM
PL
CH
EF

DATE SENT	DUE DATE	DATE RETURNED

RESPONSE CODE	RESPONSE DATE
12	6-26-81

26 Status: _____

27 FINAL Response ACTION: Code 12 Response Date

MO	07	DAY	16	YR	81
----	----	-----	----	----	----

28 75-DAY RESPONSE DUE DATE: ☐ (Y) Yes ☐ (N) No

ENFORCEMENT CASE REVIEW	
TO: Director, Pesticides Enforcement Division Office of Enforcement and General Counsel	
I.D. NO. 172045	
EPA REGISTRATION NO. See below	
PRODUCT NAME (On sample label) BON-DEL BACTERIOSTATIC WATER UNIT	
COMPANY NAME AND ADDRESS (On sample label) (Include ZIP code) Bon Del Inc. 157 S. Rosemary Mesa, AZ 85202	REGISTRATION STATUS AT TIME OF XXXXXX Collection <input type="checkbox"/> REGISTERED ★ <input type="checkbox"/> NOT REGISTERED
DISTRIBUTOR STATUS AT TIME OF SHIPMENT (If applicable)	
BASIC PRODUCT NAME	PRODUCT SUPPLEMENTALLY REGISTERED <input type="checkbox"/> YES <input type="checkbox"/> NO
FRANCHISE NAME AND ADDRESS (Include ZIP code)	DATE OF SUPPLEMENTAL REGISTRATION
OTHER PERTINENT REGISTRATION DATA <p>"The "Bacteriostatic Water Filter Media" which is used in the BON-DEL BACTERIOSTATIC WATER UNIT is registered to IONICS, Inc., P.O. Box 99, Bridgeville, PA. 15017 for product name HYGENE under EPA Reg. No. 35900-2.</p> <p>Bon Del Inc., Mesa, AZ 85202 (company number 43430) is not supplementally registered under EPA Reg. No. 35900-2. They have no registered products. They have three applications pending (1) 43430-R for BON DEL MODEL R-1, (2) 43430-E for BON DEL MODEL TR1, (3) 43430-G for BON DEL MODEL CT-5 (all applications dated 10-16-79).</p>	
IS THIS A PESTICIDE? <input checked="" type="checkbox"/> YES (If yes, list claims below) <input type="checkbox"/> NO	
PESTICIDE CLAIMS <p><i>1. bacteriostatic water filter media</i> <i>2. water purifier</i> <i>3. water purifier</i> <i>4. water purifier</i> <i>5. water purifier</i> <i>6. water purifier</i> <i>7. water purifier</i> <i>8. water purifier</i> <i>9. water purifier</i> <i>10. water purifier</i></p>	
SIGNATURE OF BRANCH CHIEF (Registration Div., Office of Pesticides Programs) Edward L. Burch Enforcement Coordinator - Registration	DATE 11/1/79



IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

October 8, 1975

CERTIFIED MAIL - RETURN RECEIPT REQUESTED
DELIVER TO ADDRESSEE ONLY

Mr. E. F. Brown
Chief, Disinfectants Branch
Registration Division (WH-567)
United States Environmental Protection Agency
401 M Street S.W.
Washington, D. C. 20460

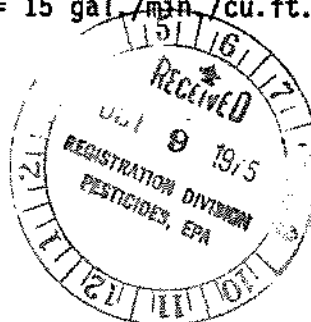
SUBJECT: HYGENE - Ionics File Symbol 35900-E
Ionics EPA Registration No. 35900-2

Dear Mr. Brown:

This letter will confirm our telephone conversation of Friday, October 3, 1975. From this phone conversation it is my understanding that the United States Environmental Protection Agency will issue to Ionics, Incorporated on their product HYgene EPA Registration No. 35900-2. This number will be issued as soon as you receive the enclosed (5) labels that have the following revisions from the original label sent to Mr. James H. Banks on September 3, 1975.

The revisions on the labels are as follows:

1. We have changed the word "Self-sanitizing" to "Bacteriostatic".
2. We have changed the claim "Prevents the growth of bacteria" to "Inhibits the growth of bacteria".
3. We have deleted "As a sanitizer".
4. We are providing the following necessary calculations to verify that the flow rate of 15 gpm/cu.ft. recommended on the label is comparable to the flow rate used in our laboratory experimentation studies. In these studies we used 500 ml./min. flow through a column of 250 cc of HYgene mineral. This is directly proportional to 15 gpm/cu.ft. of HYgene as follows:
 - a. $500 \text{ ml./min.} = 0.132 \text{ gpm}$
 - b. $250 \text{ cc HYgene} = 0.008828 \text{ cu.ft.}$
 - c. $0.132 \text{ gal./min.} / 0.008828 \text{ cu.ft.} = 15 \text{ gal./min./cu.ft.}$
by direct proportion.



*Superseded by
submission of
10-14-75
RGP*

Mr. E. F. Brown
Chief, Disinfectants Branch
Registration Division (WH-567)
United States Environmental Protection Agency

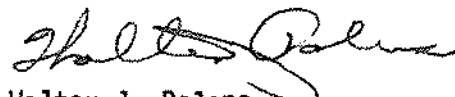
October 8, 1975
Page 2

It is our understanding that we are to provide you with copies of any collateral literature such as technical bulletins and brochures distributed in connection with this product for your review. At the present we have no literature that will be sent with the product. We are enclosing a copy of a letter we are sending to some of our potential customers.

I would like to take this opportunity to thank you and all of your staff for the cooperation we received.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

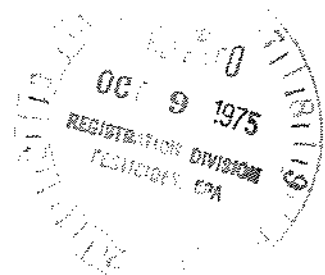


Walter J. Polens
Vice President

WJP:mle

Enclosures

cc: Mr. James H. Banks





P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5108973299

Water Conditioning Equipment • Custom Fabrication for the Nuclear, Chemical & Food Industries • Heat Transfer Equipment

This letter is to inform you that Ionics, Incorporated has been granted its Federal Registration Number from the Environmental Protection Agency for its product HYgene.

HYgene has been registered under the Federal Insecticide/Fungicide/Rodenticide Act and has received a Bacteriostatic rating. The Federal Government allows us to make the following claim - that our product will inhibit the growth of bacteria.

We can now honor all purchase orders and make immediate shipment of this product.

We are enclosing our current O.E.M. price list.

May we look forward to hearing from you with your requirements.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle

Enclosure



Ionics, Incorporated
P.O. Box 99
Routes 519 & 50
Bridgeville, PA 15077

Attention: Walter Polens


Gentlemen:

Subject: Hygiene Bacteriostatic Water Filter Media
EPA Registration No.: 15900-2
Amendment Application Date: June 12, 1981

A preliminary review of the subject application has been made. However, before the amendment can be processed further, clarification is needed in the following regard.

- (a) Please explain if 1.05% as declared on the label is that of "Silver" or is it "Silver nitrate Your label accepted October 29, 1975 declared "Metallic silver - - - 1.05%."
- (b) Is it the same product? Please clarify.
- (c) If your label declares "silver" from "silver nitrate" then you may declare no more than 0.67%. Explain why you wish to change your formulation?

Sincerely,

John H. Lee 
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)

EPA:TS-767C:JHLEE:46073:1725A:479-2018:7/6/81

17 JUL 1981

HYgene Mark I

BACTERIOSTATIC WATER FILTER MEDIA

Removes objectionable tastes, odors, color from treated municipally—supplied tap water.

Inhibits the growth of bacteria within the filter media bed.

CAUTION: KEEP OUT OF REACH OF CHILDREN

EPA Reg. No. 35900—2 EPA Est. No. 35900 PA.01.

ACTIVE INGREDIENT

SILVER as AgNO_3 ——— 1.05 % LOT No. _____

INERT INGREDIENT

ACTIVATED CARBON---98.95 % NET CONTENTS _____cu. ft.

STORAGE ————— Store in closed container which excludes moisture and fumes.

DIRECTIONS FOR USE ————— Refer to enclosed product data sheet.

DISPOSAL OF SPENT MEDIA --- Retain Shipping carton and liner for disposing of exhausted filter media with trash.

USE ————— This product is to be used only for manufacturing or fabricating Bacteriostatic Water Filter Products for home use.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment.

IONICS, INC. Routes 519 & 50 P.O. Box 99 Bridgeville, Pa. 15017

0 1 2 3 4

5 6 7 8 9

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1000

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0100
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Another fine product by the manufacturers of General Ionics Water Conditioning Equipment.

IONICS, INC. Routes 519 & 50 P.O. Box 99 Bridgeville, Pa. 15017

0.10.01
0.10.01

ENFORCEMENT CASE REVIEW
(Test and Label)

ID NUMBER

EC-79-28

EPA REGISTRATION NUMBER

35800-2

TYPE OF REVIEW

☒ CHEMISTRY

☐ EFFICACY

☐ SAFETY

☐ OTHER (Specify)

TEST RESULTS AND SIGNIFICANCE

No Analysis performed

LABELING REVIEW

ARE THERE ANY SIGNIFICANT LABELING DEFECTS?

☒ YES (If yes, list substantial discrepancies and significances below)

☐ NO

DATE OF ACCEPTANCE OF
APPLICABLE LABELING

10-29-75

SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES

See D.M. Portner's review

Shawell

5-31-79

ENFORCEMENT CASE REVIEW
(Test and Label)

ID NUMBER

EC-79-28

EPA REGISTRATION NUMBER

None

TYPE OF REVIEW

CHEMISTRY



EFFICACY

SAFETY

OTHER (Specify)

TEST RESULTS AND SIGNIFICANCE

The following claims on the labeling are considered under the provisions indicated in Section 162.10(a)(5) of the Regulations for Enforcement of FIFRA as false and misleading statements:

1. The pesticidal claims for disinfecting water and killing 100% bacteria exceed the effectiveness of the silver impregnated water filter media, "Hygen", incorporated in this water treatment device.
2. The non-pesticidal claims for removal of "Insecticides such as 1. Chlorobenzene ... 9. Toxaphene", "Industrial chemicals and solvents such as 1. Acetophenone ... 7. propylene chlorohydrin", "inorganic inorganics found in water such as 2. Arsenic ... 5. Mercury" exceed the value of this water filter media for such purposes.
3. The claim "The applications, testing and performance of the media"

LABELING REVIEW

ARE THERE ANY SIGNIFICANT LABELING DEFECTS?

☐

YES (If yes, list substantial discrepancies and significances below)

☐

NO

DATE OF ACCEPTANCE OF APPLICABLE LABELING

SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES

has been approved by the Environmental Protection Agency (EPA # 35400-2) "emphasize recommendation or endorsement by EPA."

4. Articles from Grand Housekeeping, Empire, Phoenix Gazette, mass Tribune and other newspapers, which accompanied the sample labeling, gave false or misleading impression to the purchaser that the sample product would be effective in eliminating the pollutants from drinking water.
5. The sample label bears the EPA Registration number for the water filter media used in this device, but no EPA Registration number for the pesticidal device itself.

D M Portner
microbiologist
5-30-79

DBH



IONICS
IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

January 13, 1977

Mr. E. F. Brown
Chief, Disinfectants Branch
Registration Division (WH-567)
U. S. Environmental Protection Agency
401 M Street S. W.
Washington, D. C. 20460

Dear Mr. Brown:

This letter will authorize you to use any information that is in Ionics, Incorporated's file, our EPA Registration 35900-2, to support registration of additional products for [REDACTED]

This letter does not, however, allow you to make public to [REDACTED] or anyone else any information in our file that would be considered proprietary information or confidential.

We thank you very much for your cooperation in this matter.

Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle

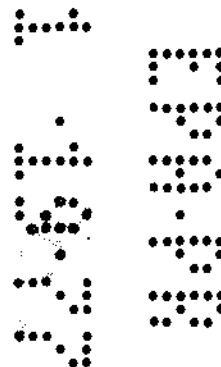
cc: James H. Banks - EPA

[REDACTED]
J. D. Collins - Ionics

PM 33

*Please place in
EPA Reg No. 35900-2*

Brown
1/18



RECEIVED
JAN 1 1964
U.S. DEPARTMENT OF AGRICULTURE
WASHINGTON, D.C.

DEC 21 1976

IONICS, INCORPORATED
Attn: Walter J. Polens
P.O. Box 99
Bridgeville, PA 15017

Dear Mr. Polens:

This is to acknowledge receipt of your letter of June 22, 1976 regarding the Volhard Method of Analysis. According to your letter it is our understanding that the Atomic Absorption Method of Analysis is being used by you or your agent(s) to analyze the "Hygene Bacteriostatic Water Filter Media" for silver content rather than the Volhard Method of Analysis. If our understanding of this matter is incorrect, please correct us.

Sincerely,

James H. Banks
Product Manager 33
Disinfectants Branch
Registration Division (WH-567)

WH-567:DLS:RDB:nd:59040:Rm 321 12/17/76

REGISTRATION DIVISION

JUN 01 1976

IONICS, INC.
Attn: Walter J. Polons
P.O. Box 99
Bridgeville, PA 15017

Gentlemen:

Subject : LETTER OF May 11, 1976

The information submitted with your letter of May 11, 1976 regarding the Atomic Absorption Method of Analysis is acceptable. However, in order to satisfy the general chemistry data requirements, you must submit details of the Volhard Method of Analysis as also requested in our letter of April 28, 1976.

Sincerely,

James H. Banks *JHB*
Product Manager 33
Disinfectants Branch (MI-567)

MI-567:DIS:RSD:md:59040:Rm 321

6/28/76

SUBMISSION REVIEW RECORD			1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED		
3. 3CID PUBLICATION NECESSARY			4. PETITION NO.				5. RECEIVED PM TEAM			
6. METHOD OF SUPPORT			7. PRODUCT MANAGER				NO.	8. PROJECTED RETURN		
9. DATE PULLED			10. DATE PUBLISHED				11. ACTION TYPE			
12. OUTGOING DATE			13. DATE REVIEW COMPLETED				14. DATE REVIEW COMPLETED			
REV. SEC.	REVIEW CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER			COM. MENT CODE	MO	DAY	YR
X	A	REVIEWABILITY TEAM	JHP	J. H. P.			MAC	05	26	76
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW								
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW								
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW								
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW	RGD	R. Douglas			PL	05	28	76
	F	PRODUCT MANAGER								
	G	INTERAGENCY REFERRAL								
	H	COST-BENEFIT REVIEW								
	I	PUBLIC COMMENTS REVIEW								
	J	EEE BRANCH INSECTICIDE EFFICACY								
	K	EEE BRANCH HERBICIDE EFFICACY								
	L	EEE BRANCH FUNGICIDE EFFICACY								
	M	EEE BRANCH RODENTICIDE EFFICACY								
	N	EEE BRANCH DISINFECTANT EFFICACY								
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY								
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY								
	Q	TOXICOLOGY BRANCH HUMAN SAFETY								
	R	EEE BRANCH ENVIRONMENTAL SAFETY								
	S									
	T									
PRODUCT MANAGER SIGNATURE			TYPE OF RESPONSE						CODE	
James H. Banks			Reg. Ltr.						B/L	

SAMPLE SUMMARY ANALYTICAL REPORT	DATE RECEIVED 4/21/76	REGISTRATION NO. 35900-2	SAMPLE NO. 112876
	PRODUCT Hygene Bacteriostatic Water Filter Media		
SEALED Seal broken by Dallas Wright, Jr.			
IDENTIFIED "SN 112876 03-23-76 ALDP Sub 1"			
RECEIVED FROM Dallas Wright, Jr. by hand	CONDITION OF SEALS Broken		LABELING SUBMITTED
DESCRIPTION OF SAMPLE Plastic bag containing broken seal and one 7 oz. plastic bottle with label. Code "Lot No. 03226 B"			
APPEARANCE Black granular solid; no odor			
ANALYSIS	AMOUNT CLAIMED	SATISFACTORY	UNSATISFACTORY
<p>Method: Silver extracted from sample with 1+1 Nitric Acid by shaking 3 hours and standing over weekend. Excess sodium chloride solution added to an aliquot of sample extract; excess titrated with silver nitrate potentiometrically. Silver in sample calculated as metallic silver.</p> <p>Results: 1 - 2.06% 2 - 1.72% 3 - 1.91%</p> <p style="text-align: center;">average - 1.90% silver (as metallic) Claim 1.05% metallic silver</p>			
SIGNATURE OF ANALYST Jack B. Looker <i>JBL</i>		DATE REPORTED 4/27/76	
RESERVE SAMPLE As rec'd <small>SEALED</small> less 30-35 grams		"112876 4-27-76 Jack B. Looker"	
SIGNATURE OF SUPERVISOR C. H. Hall		DATE 4-27-76	



UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

REPORT OF ANALYSIS

1. SAMPLE NO.
112876

2. DATE COLLECTED
3-23-76

3. REGION
III

SAMPLE IDENTIFICATION

4. LOT OR CODE NO(S).

032268

5. EPA REGISTRATION NO.

33900-2

6. ESTABLISHMENT NO.

33900-PA-01

7. PRODUCT NAME

"HYGHE Bacteriostatic Water Filter Media"

8. PRODUCER NAME AND ADDRESS (Include ZIP code)

**IONICS, INC.
Routes 519 and 50
Bridgeville, Penna. 15017**

9. DEALER NAME AND ADDRESS (Include ZIP code)

10. PHYSICAL FORM

EMULS. CONC.

PRESS. SPRAY

DUST

☒ GRANULAR

WET. POWDER

AEROSOL

BAIT

OTHER

11. INGREDIENTS

**Silver (Metallic) 1.05%
Activated Carbon 98.95%**

TEST

12. TYPE OF TEST

Agar Cup

13. TEST ORGANISM(S)

**E. coli
Staph. aureus
Pseudomonas fluorescens**

14. METHOD NO.

TAB

4,201

15. DURATION

24 hrs

16. CONCENTRATION

17. DILUENT

18. SUMMARY

**Sample was found to possess bacteriostatic activity against
Escherichia coli, Staph aureus and Pseudomonas fluorescens.**

19. RESULTS

**Zones of inhibition against: Escherichia coli 1 mm
Staphylococcus aureus 1 mm
Pseudomonas fluorescens 1 mm**

20. TESTER'S INITS.

21. SIGNATURE OF LAB SUPERVISOR

22. LABORATORY

23. DATE

REGISTRATION DIVISION

IONICS, INCORPORATED
Attn: Walter Polans
P.O. BOX 99
Bridgeville, PA 15017

APR 28 1975

Gentlemen:

Subject: HYGENE
EPA Reg. No. 35900-2
Your letters of February 18, 19, 1975 and
March 4, 1975

The general chemistry data is acceptable with the exception of A.5 and B.4. You should submit details of the atomic absorption and the Volhard Methods of Analysis.

In regards to your suggested procedure for evaluation of Hygene Model HW-2 cartridge type filter for EPA Registration. Data derived in accordance with the test protocol submitted would meet the bacteriostatic efficacy data requirements indicated in our letter of December 24, 1975 for a unit which processed municipally treated tap water at a flow rate of 3 gpm for a 18,750-gallon volume capacity. The acceptance of the unit for the efficacy claimed is contingent upon the subsequent evaluation of the data developed in concurrence with labeling claims.

A copy of our recently prepared document "Interim Requirements For Registering Bacteriostatic Water Treatment Units for Home Use" is enclosed to inform you of the test protocol to be used in testing future water treatment units that you develop. At this interim interval, you have the option of developing data by either the test protocol that you submitted or by the one indicated in the document enclosed.

Your submission of December 5, 1975, in reference to Pool Gene, File Symbol 35900-R, is still under review. Due to the nature of the points raised and/or objections stated in your letter in reference to our previous evaluation of your application, it was deemed necessary that each of the five scientific disciplines concerned render their scientific

judgement. Three such evaluations have been made. However, two more are still required. As soon as we have received a response from all of the disciplines involved, the information will be transmitted to you. We expect this review to be completed in approximately two weeks.

Sincerely,

JHB
James H. Banks
Product Manager 33
Disinfectants Branch (WI-567)

Enclosure

WI-567:DIS:RBD:md:59040:Rm 321 4/23/76

JAN 20 1976

Ionics, Incorporated
Attn: Walter Polans
P.O. Box 99
Bridgeville, PA 15017

Dear Sir:

Subject: Hygene
EPA Reg. No. 35900-2

We will accept your general chemistry data for HYGENE media and all products using your media if you verify that the following information is correct:

A.1 Complete composition of technical chemical used as active ingredient:

**Essentially 100% metallic silver formed in situ,
with only traces of impurities.**

A.2 Manufacturing process of the technical chemical:

Same as in Petition 515079

A.3 Purity of starting and intermediate materials used in the manufacturing process:



A.4 Basic physical and chemical characteristics of the active ingredient(s):

Malleable, ductile, metallic, heavy, sensitive to light

Page 2

A.5 Details of the atomic absorption and the Volhard methods of analysis
& will be submitted soon.

B.4

Your immediate response to this letter is requested.

Sincerely,


James H. Banks
Product Manager (33)
Disinfectants Branch
Registration Division (MI-567)

MI-567::DB:JHBKS:bab:rm 21949E, #58315:1/16/78

REGISTRATION DIVISION

DEC 24 1975

IONICS, INCORPORATED
Attn: Walter J. Polans
P.O. Box 99
Bridgeville, PA 15017

Gentlemen:

Subject : HYGENE
EPA Reg. No. 35900-2
Your letter of December 3, 1975

This is in response to your letter of December 3, 1975 in reference to your proposed product named HT2 Water Cleaner.

Although we do expect good engineering principles to be applied to water treatment products utilizing silver filtering media, interpolation and/or extrapolation of data developed to demonstrate efficacy of the filtering media per se is not acceptable to substantiate efficacy of a specific water treatment product.

Silver release data for 10 product units and bacteriological data for 3 product units and 3 corresponding activated carbon controls must be provided to substantiate efficacy of the product identified as "HT2 Water Cleaner" when manufactured with silver filtering media.

Data developed over the lifetime of the product must be provided to support claims for the removal of pesticides, phenols, and detergents.

The earlier information provided that separate EPA Registration Numbers will be required for each individual water treatment product, including replacement filters still applies. The registration number issued (EPA Reg. No. 35900-2) only covers the production and sale of the HYGENE medium and should not be misconstrued as pertaining to any individually manufactured water treatment unit.

Sincerely,

James H. Banks *JHB*
Product Manager 33
Disinfectants Branch (EH-567)

EH-567:DLE:RSD:md:59040:12-23-75:lha 321



IONICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

December 3, 1975

United States Environmental Protection Agency
Disinfectants Branch, Room 371
Registration Division (MD-667)
OPP-EPA
401 M Street S. W.
Washington, D. C. 20540

Attention: Mr. James Banks

Dear Mr. Banks:

This letter will authorize you to use information in our file under our EPA Registration No. 35900-2 for the evaluation of a water filter manufactured by [REDACTED]

This letter gives you authorization to refer to our file but not to make available to [REDACTED] any confidential material in the file.

If you have any questions concerning this, please contact me.

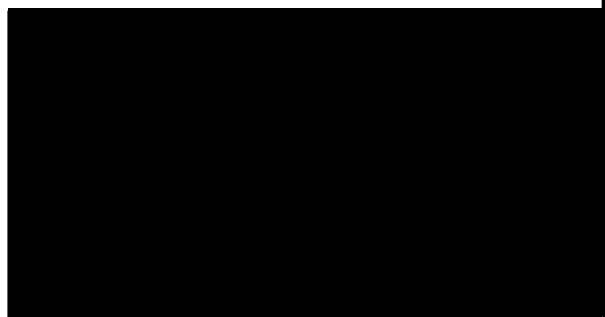
Very truly yours,

IONICS, INCORPORATED
Bridgeville Plant

Walter J. Polens
Vice President

WJP:mle

cc: [REDACTED]



REGISTRATION DIVISION

IONICS, INCORPORATED
Attn: Walter J. Polens
P.O. Box 99
Bridgeville, PA 15017

DEC 04 1975

Gentlemen:

Subject : HYGENE
EPA Reg. No. 35900-2
Your letter of November 13, 1975

The general chemistry information submitted with the referenced letter in support of [REDACTED] application, File No. [REDACTED] is not acceptable.

Apparently you did not quite understand our request. The general chemistry requirements are in two (2) parts. The first part, (A), refers to the technical chemical used as the active ingredient (in this case-- elemental silver) and the second part, (B), refers to the specific pesticide formulation (in this case-- a water filter containing silver and carbon). The information required is as follows:

- A. Information on the technical chemicals used as the active ingredients in the pesticide, including:
 - 1. Complete composition of the technical chemical, including the chemical names and percentages of impurities;
 - 2. Basic manufacturing process of the technical chemical.
 - 3. Purity of starting and intermediate materials used in the manufacturing process;
 - 4. Basic physical and chemical characteristics of the active ingredient(s), either in technical or purer form;
 - 5. Analytical methods for the principal component(s) and impurities.
- B. Information on the specific pesticide formulation including:
 - 1. Method(s) of analysis for identifying and quantifying the active ingredient(s) in the pesticide formulation.

2. Note that "basic physical and chemical characteristics", in A(4) above, mean - structural formula, melting point, boiling point, vapor pressure, density, hydrolysis rate, solubility, dissociation constants, stability, physical state, color and odor. You have not supplied any of this information.

3. Submit more details of the atomic absorption method.

4. We accept your storage stability data as satisfactory.

5. Your attachment A(Method for determining total silver content of Hygene) is not acceptable because it is incomplete. Exactly how do you analyze for silver? You say "Take aliquot for quantitative analyses of silver." However, that is the end of the method. Please explain.

Sincerely,


James H. Banks
Product Manager 33
Disinfectants Branch (MH-567)

MH-567:DIS:RBD:md:59040:12-2-75:Rm 321

Note to File

Letter dated 11-13-75
has been placed in the
"Confidential" envelope.

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION
WASHINGTON, D.C. 20460

EPA REGISTRATION NUMBER

DATE OF ISSUANCE

NAME OF PESTICIDE PRODUCT

NOTICE OF REGISTRATION

*(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)*

NAME AND ADDRESS OF REGISTRANT

F

L

OCT 25 1975

NOTE: Changes in labeling or formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of the information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this registration is returned herewith.

Registration is in no way to be construed as an endorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The following paragraphs are applicable only when checked:

☐ The registration for this product is being issued with the understanding that certain defects in the labeling which are noted below will be corrected as soon as possible. Objection is not raised to the use of the present labeling for a reasonable period of time while fully corrected labeling is being prepared. Three copies of the corrected labeling must be submitted.

☐

☐ Attachment is applicable.

SIGNATURE OF APPROVING OFFICIAL

DATE

2

Note that this submission was processed and accepted under current requirements. At such time as re-registration is required or amendments are proposed, the Registration, Re-registration and Classification Procedures, as published in the Federal Register on July 3, 1975, will be applied. Refer to Section 162.23 of that document. Refer also to PR Notice 75-1.

Sincerely,



James H. Banks
Product Manager 33
Disinfectants Branch
Registration Division

Enclosure



Stamped Label

WH-567:DIS:RDOUGLAS:ca:10/29/75:R59041:rm-321

cc: PED



ACCEPTED

BACTERIOSTATIC WATER FILTER MEDIA

Inhibits the growth of bacteria

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and chemical fumes

EPA Reg. No. 35900-2

EPA Est. No. 35900 PA 01

ACTIVE INGREDIENT

METALLIC SILVER

INERT INGREDIENT

ACTIVATED CARBON

DIRECTIONS FOR USE:

1.05% LOT NO.

NET CONTENTS

Flow rate is not to exceed 15 GPM per cu. ft. of media. Bed depth must be at least twice the diameter.

DISPOSAL OF SPENT MEDIA:

Retain shipping carton and plastic liner for disposing of exhausted filter media with trash.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment
IONICS, INCORPORATED Routes 519 & 50, Bridgeville, Penna. 15017

35900-2

FILMED - 1976

Rehab Group Inc. Arlington, Va.
(703) 521-7800 Zip 22204

REGISTRATION DIVISION

IONICS, INC.
Attn: Walter J. Polons
P.O. Box 99
Bridgville, PA 15017

OCT 09 1975

Gentlemen:

Subject : HYGIENE
File Symbol 35900-E
Your submission of September 3, 1975

The product referred to above will be acceptable for registration under the Federal Insecticide, Fungicide, and Rodenticide Act; provided, finished labeling is submitted incorporating the following revisions.

1. Change "Self-sanitizing" to read "bacteriostatic". ✓
2. Change the claim "Prevent the growth of bacteria" to read "Inhibits the growth of bacteria." ✓
3. Delete "as a sanitizer." ✓
4. Note the correct spelling of silver.
5. Provide the necessary calculations to verify that the flow rate recommended on the label is comparable to the flow rate used in these laboratory experimentation studies.
6. Any collateral literature, such as technical bulletins or brochures, distributed in conjunction with this product must be submitted for review. ?

Based on an evaluation of the data submitted, the following conclusions were made:

- A. Claims supported by data: The requirement to demonstrate that the silver concentration of the effluent water does not exceed 50 ppb after treatment is fulfilled by the chemical data provided.
- B. Data not appropriate: The bacteriological data are inappropriate to support a self-sanitizing claim for filter media. To support such a claim, a study must be designed to demonstrate (1) that the filter media does retain bacteria in sufficient number and (2) that the filter media does effectively and significantly reduce the bacterial population retained.

- C. Lesser claim the data will support: The data provided suggest inhibition of bacterial growth in water stagnated within the filter media for 10 hours.
- D. Additional information required: To substantiate the bacteriostatic claim for the filter media, the following additional information must be provided:
- 1) The concentration of the artificially contaminated water (inoculum) at the end of the test is required to ascertain the degree of natural "dieoff".
 - 2) The neutralizer used must be identified.
 - 3) Determinations of the silver content in the effluent from the three test units used to derive the bacteriological data are required.
 - 4) Bacteriological assay method used to derive counts on the effluent from the control and test units must be submitted.

FDA Reg. No. 35900-2" is being reserved for this product. This must appear on the finished label. The "Notice of Registration" will be issued when five (5) copies of the acceptable finished (printed) labeling are submitted. Finished labeling is that which will be attached to or accompany the product. Refer to the attached A-79 Enclosure.

To expedite handling, please return the enclosed duplicate copy of this letter with your finished labeling.

This letter does not constitute registration, and the product may not be lawfully marketed in interstate commerce until it is registered.

Sincerely,



James H. Banks
Product Manager 33
Disinfectants Branch (MH-567)

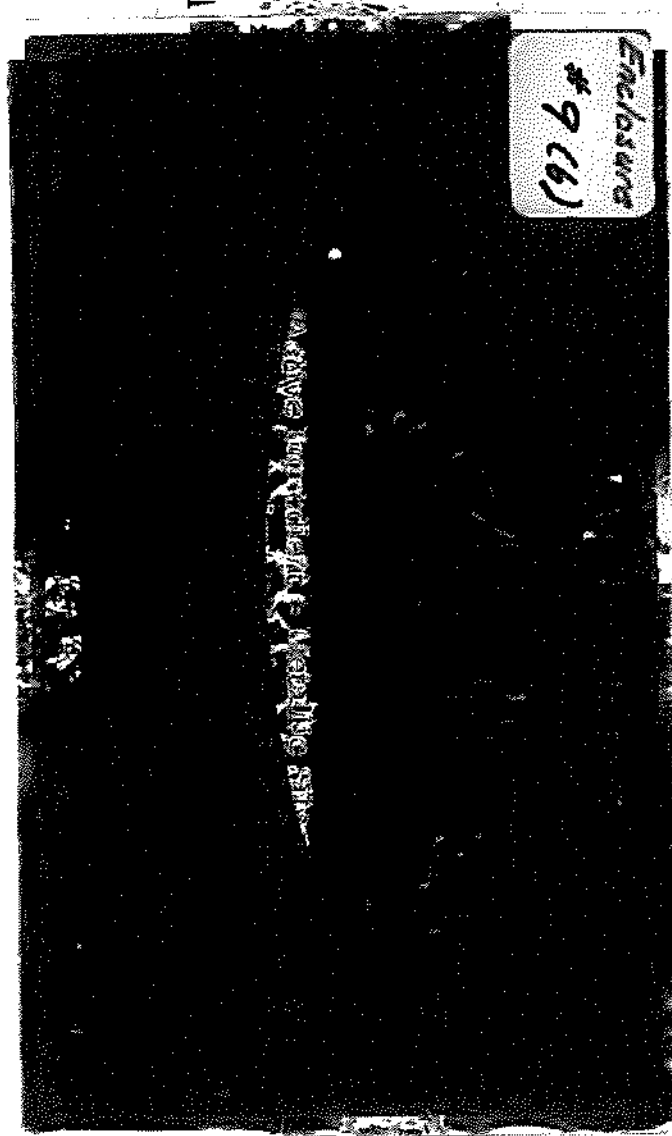
Enclosure

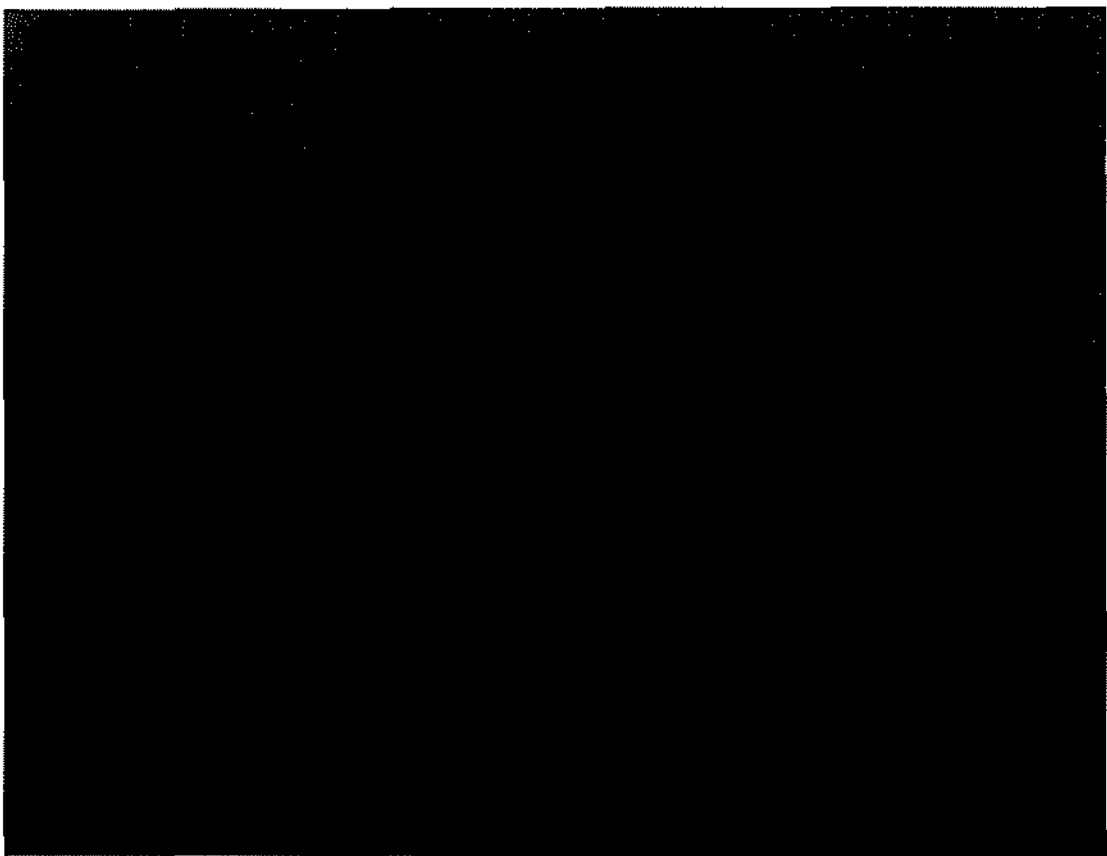
A-79 Encl.
Duplicate letter

MH-567:DIS:RGD:nd:59040:10-9-75:fm 321

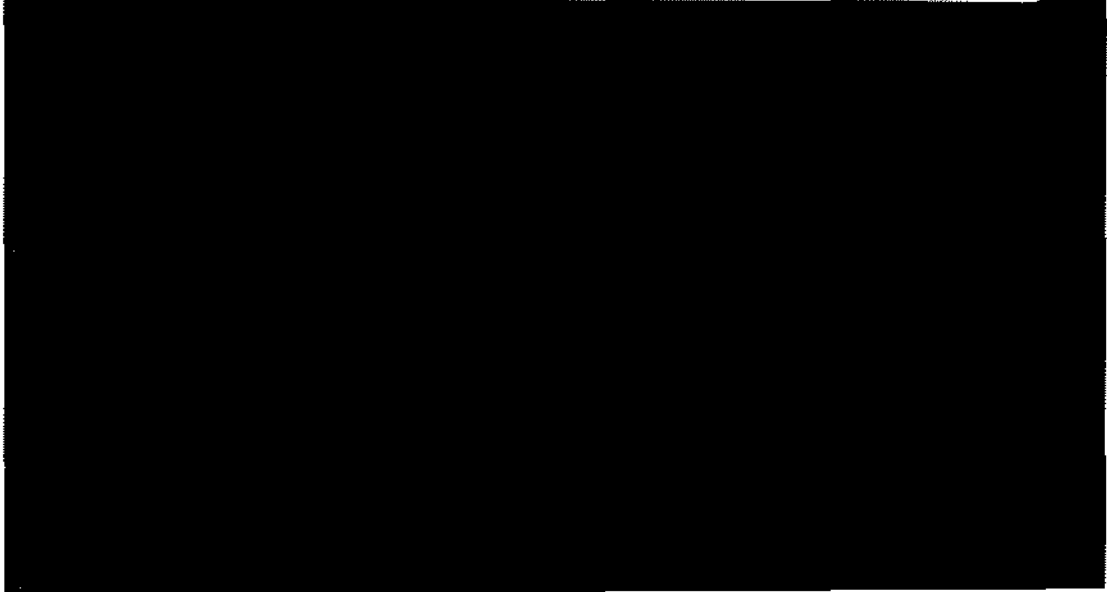
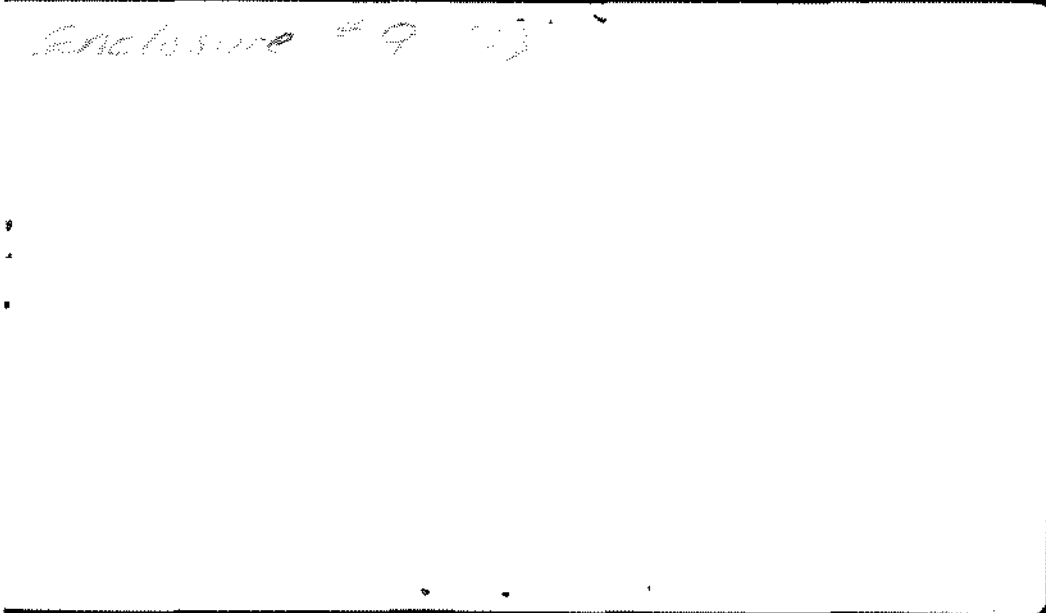
Enclosure # 9 (b)

2/27/75





Enclosure #9 13



Enclosure # 9 (6)

2/27/75

...

...

...

...

Enclosure # 9 (a)



WATER PURIFICATION MEDIA

- Disinfects without the use of chlorine
- Produces potable water to meet USPH standards
- Removes objectionable taste, odor and color

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and chemical fumes.

Active Ingredient - Metallic Silver	1.05%
Inert Ingredient - Activated Carbon	98.05%

Contents: _____ cu. ft.

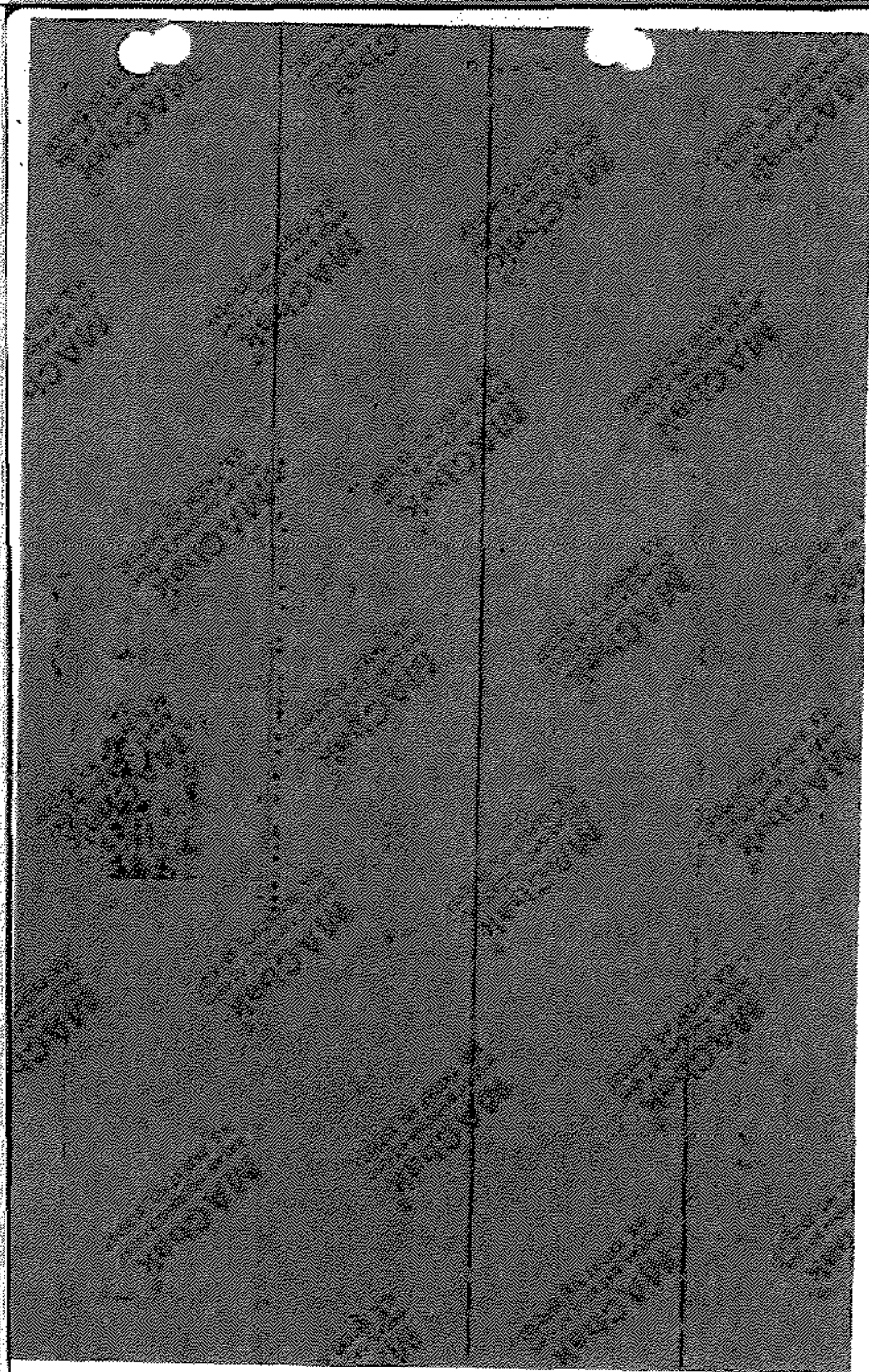
Lot No. _____

Code _____

- Another fine product by the manufacturers of General Ionics Water Conditioning Equipment

IONICS, INCORPORATED / Routes 519 & 50, Bridgeville, Pennsylvania 15017

© Trademark registered



Enclosure # 9 (a)

2/27/75

REGISTRATION DIVISION

JUL 25 1975

IONICS, INCORPORATED
Attn: Walter J. Polans
P.O. Box 99
Bridgeville, PA 15017

Gentlemen:

Subject : IONICS
File Symbol 33900-E
Your application of February 10, 1975

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable, for the reasons given below.

1. The data submitted do not support claims of efficacy for this product as a water purifier. Submit chemical and bacteriological data developed in accordance with the procedures outlined in Part VII A and B of the document "Interim Standards for Water Purifier" enclosed hereto.
2. Submit labeling amended to include only bacteriological efficacy claims delineated in Part VI of this document.
3. The labeling submitted must be amended to include mandatory labeling requirements as indicated below:

A. On the front panel:

1. An acceptable product name. (The present name is acceptable)
2. The ingredient statement must appear on the front panel, or that part of the label displayed under customary conditions of purchase. Also, the ingredient statement must be clear on a contrasting background, not obscured or crowded.
3. The word "CAUTION" followed by the referenced "Keep Out of Reach of Children" Note. These must appear in proper type size as indicated on the "Front Panel Precautionary Labeling Requirements" enclosure.
4. A statement of net contents, as for example "Net Contents: 1 water purifier unit."

B. The following may appear elsewhere on the label:

1. The name and address of the registrant.
2. A container disposal statement somewhat as "Wrap spent purifier unit in newspaper and discard with trash."
3. Directions for use or a statement setting forth where such directions may be found such as "See enclosed circular (or leaflet or bulletin) for directions for use."
4. The assigned EPA Reg. No.
5. The EPA Est. No.

This product may not be lawfully distributed in interstate commerce until it is registered.

Sincerely,

RGD
James H. Banks
Product Manager 33
Disinfectants Branch (WH-567)

Enclosure

WH-567:DIS:RGD:md:7-23-75:59040:Rm 321

2-A

2-B

2-C

Review under revised Sec. 3 Reg. Yes No

Date of Submission: 12-3-75 Reg/EXP

Petition No.

Product Name H12 Water Cleaner

Company Anies Inc.

Type of Product: I R H F D

Product Manager (name): Banks

Type Submission- Rm# 321

Petition

New Product -New Chem.

New Product Old Chem

Amended Reg. Substantive

Amended Reg. Nonsubstantive

Reviews Needed

Rec'd by E. Gross

Sent to Reviewer

Date Completed

Returned to PM

RET

Completeness Review

Data Review

Waiver Reg.

Review Labeling

Letter

EEEB

EFFACY

Completeness Review X

Data Review

Waiver Reg.

Review Labeling

Letter Comment on Mr. of 12-3-75

F&W

Completeness Review

Data Review

Waiver Reg.

Review Labeling

Letter

E CHEM.

Completeness Review

Data Review

Waiver Reg.

Review Labeling

Letter

TOX BR.

Completeness Review

Data Review

Waiver Reg.

Review Labeling

Letter

CHEM BR.

Completeness Review

Data Review

Waiver Reg.

Review Labeling

SUBMISSION REVIEW RECORD			1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED			
G			35900 -				E	090575			
3. SCIO PUBLICATION NECESSARY <input type="checkbox"/> YES <input type="checkbox"/> NO			4. PETITION NO.				5. RECEIVED PM TEAM MO DAY YR				
6. METHOD OF SUPPORT <input type="checkbox"/> 2A <input type="checkbox"/> 2B <input checked="" type="checkbox"/> 2C			7. PRODUCT MANAGER James H. Banks				NO.	8. PROJECTED RETURN MO DAY YR			
9. DATE PULLED		10. DATE PUBLISHED	11. ACTION TYPE				CODE	12. OUTGOING DATE MO DAY YR			
		3-24-75	Resubmission				512				
REV. SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COM. MENT CODE	DATE REVIEW COMPLETED MO DAY YR					
	A	REVIEWABILITY TEAM									
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW									
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW									
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW									
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW									
	F	PRODUCT MANAGER									
	G	INTERAGENCY REFERRAL									
	H	COST-BENEFIT REVIEW									
	I	PUBLIC COMMENTS REVIEW									
	J	EEE BRANCH INSECTICIDE EFFICACY									
	K	EEE BRANCH HERBICIDE EFFICACY									
	L	EEE BRANCH FUNGICIDE EFFICACY									
	M	EEE BRANCH ROENTICIDE EFFICACY									
✓	N	EEE BRANCH DISINFECTANT EFFICACY	DMIP	DM Portner		019	310	715			
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	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY									
	Q	TOXICOLOGY BRANCH HUMAN SAFETY									
	R	EEE BRANCH ENVIRONMENTAL SAFETY									
	S										
	T										
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE			CODE				

SUBMISSION REVIEW RECORD				1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED		
3. 3CID PUBLICATION NECESSARY				4. PETITION NO.				5. RECEIVED PM TEAM			
6. METHOD OF SUPPORT				7. PRODUCT MANAGER				NO.	8. PROJECTED RETURN		
9. DATE PULLED		10. DATE PUBLISHED		11. ACTION TYPE				CODE	12. OUTGOING DATE		
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3-24-85		3-24-85		Resubmission				52			
REV. SEC.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER				CDM-MENT CODE	DATE REVIEW COMPLETED		
	A	REVIEWABILITY TEAM							MO	DAY	YR
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW									
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW									
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW									
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW									
	F	PRODUCT MANAGER									
	G	INTERAGENCY REFERRAL									
	H	COST-BENEFIT REVIEW									
	I	PUBLIC COMMENTS REVIEW									
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PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE				CODE			

SUBMISSION REVIEW RECORD			1. REGISTRATION NUMBER		CYCLE	2. DATE RECEIVED			
3. 3CID PUBLICATION NECESSARY			4. PETITION NO.			5. RECEIVED PM TEAM			
6. METHOD OF SUPPORT			7. PRODUCT MANAGER			NO.	8. PROJECTED RETURN		
9. DATE PULLED		10. DATE PUBLISHED	11. ACTION TYPE			CODE	12. OUTGOING DATE		
<input type="checkbox"/> YES <input type="checkbox"/> NO									
<input type="checkbox"/> 2A <input type="checkbox"/> 2B <input checked="" type="checkbox"/> 2C			James H. Fink			33			
		3-24-75	K-P submission			52			
REV. SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COM. CODE	DATE REVIEW COMPLETED			
	A	REVIEWABILITY TEAM				MO	DAY	YR	
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW							
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW							
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW							
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW							
	F	PRODUCT MANAGER							
	G	INTERAGENCY REFERRAL							
	H	COST-BENEFIT REVIEW							
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	R	EEE BRANCH ENVIRONMENTAL SAFETY							
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	T								
PRODUCT MANAGER SIGNATURE			TYPE OF RESPONSE			CODE			

SUBMISSION REVIEW RECORD			1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED		
3. 3CID PUBLICATION NECESSARY <input type="checkbox"/> YES <input type="checkbox"/> NO			4. PETITION NO.				5. RECEIVED PM TEAM MO DAY YR	6. PROJECTED RETURN MO DAY YR		
6. METHOD OF SUPPORT <input type="checkbox"/> 2A <input type="checkbox"/> 2B <input checked="" type="checkbox"/> 2C			7. PRODUCT MANAGER James H. Hanks				NO.	8. PROJECTED RETURN MO DAY YR		
9. DATE PULLED		10. DATE PUBLISHED 3-24-75	11. ACTION TYPE Re-submission				CODE	12. OUTGOING DATE MO DAY YR		
REV. SEC.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER			COM-MENT CODE	DATE REVIEW COMPLETED MO DAY YR		
	A	REVIEWABILITY TEAM								
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW								
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW								
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW								
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW								
	F	PRODUCT MANAGER								
	G	INTERAGENCY REFERRAL								
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	I	PUBLIC COMMENTS REVIEW								
	J	EEE BRANCH INSECTICIDE EFFICACY								
	K	EEE BRANCH HERBICIDE EFFICACY								
	L	EEE BRANCH FUNGICIDE EFFICACY								
	M	EEE BRANCH RODENTICIDE EFFICACY								
	N	EEE BRANCH DISINFECTANT EFFICACY								
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY								
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY								
	Q	TOXICOLOGY BRANCH HUMAN SAFETY								
	R	EEE BRANCH ENVIRONMENTAL SAFETY								
	S									
	T									
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE				CODE		

SUBMISSION REVIEW RECORD			1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED		
3. SCID PUBLICATION NECESSARY <input type="checkbox"/> YES <input type="checkbox"/> NO			4. PETITION NO.					5. RECEIVED PM TEAM		
								MO	DAY	YR
6. METHOD OF SUPPORT <input type="checkbox"/> 2A <input type="checkbox"/> 2B <input type="checkbox"/> 2C			7. PRODUCT MANAGER <i>James - 101</i>				NO.	8. PROJECTED RETURN		
								MO	DAY	YR
9. DATE PULLED		10. DATE PUBLISHED	11. ACTION TYPE				CODE	12. OUTGOING DATE		
								MO	DAY	YR
REV. SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER			COM. CODE	DATE REVIEW COMPLETED		
								MO	DAY	YR
	A	REVIEWABILITY TEAM								
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW								
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW								
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW								
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW								
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	L	EEE BRANCH FUNGICIDE EFFICACY								
	M	EEE BRANCH RODENTICIDE EFFICACY								
	N	EEE BRANCH DISINFECTANT EFFICACY								
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY								
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY								
	Q	TOXICOLOGY BRANCH HUMAN SAFETY								
	R	EEE BRANCH ENVIRONMENTAL SAFETY								
	S									
	T									
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE				CODE		



BACTERIOSTATIC WATER FILTER MEDIA

Inhibits the growth of bacteria

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and chemical fumes.

EPA Reg. No. 35900-2

EPA Est. No. 35900 PA 01

ACTIVE INGREDIENT

METALLIC SILVER

1.05%

LOT NO.

INERT INGREDIENT

ACTIVATED CARBON

98.95%

NET CONTENTS

cu. ft.

Flow rate is not to exceed 15 GPM per

cu. ft. of media. Bed depth must be at least

twice the diameter.

Retain shipping carton and plastic liner for

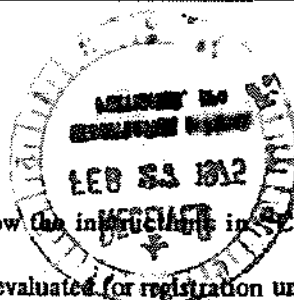
disposing of exhausted filter media with trash.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment

IONICS, INCORPORATED Routes 519 & 50, Bridgeville, Penna. 15017

Confidential Statement of Formula may be entitled to confidential treatment

INSTRUCTIONS



NOTE: Use a separate form for each Formulation.

Applicant - keep the second copy for your files and forward the original to EPA or follow the instructions in "C" below.

- A. The complete chemical composition of each pesticide must be known so it can be evaluated for registration under the Federal Insecticide, Fungicide and Rodenticide Act. This information is also necessary to determine the status of ingredients, both active and inert, under the Pesticide Chemicals Amendment to the Federal Food, Drug and Cosmetic Act.
- B. This form is designed for reporting the ingredients used in the formulation of a pesticide. Its use will speed the review. It must be completed and submitted with each EPA Form 8570-1, Application For New Registration Of A Pesticide, or with each EPA Form 8570-2, Application For Amended Registration Of A Pesticide, if revision involves a formula change, or with each EPA Form 8570-3, Application For Renewal Registration Of A Pesticide.
- C. If the complete chemical composition of formulated ingredients, either active or inert, used in this product's formulation is not known to you, send a separate set of these forms for each ingredient to your Basic Supplier. When you do this, it is important that you first fill in items 2 thru 8 so that we may positively identify the supplier's product with your pesticide. The Basic Supplier is then requested to complete items 1, and 9 thru 15, and submit the form to this Division. This statement is treated confidentially. It cannot be used to support a customer's (formulator's) application for subsequent registration without written authorization from the Basic Supplier.

ITEM No.

- 1. If more than 1 page is required, number them "1 of 2", "1 of 3", etc.
- 2. Enter the same date as the Application.
- 3. Read instruction "B" above.
- 4. Enter the name and address of your firm.
- 5. Enter the product name of this pesticide as it will appear on the finished label.
- 6. Enter the EPA Registration Number or File Symbol if known.
- 7. Complete if required by instruction "C" above.
- 8. Complete if required by instruction "C" above.
- 9. Completed only by Basic Supplier.
- 10. Completed only by Basic Supplier.
- 11. List first all active ingredients then the inert ingredients each in the exact order as they will appear on the finished label. When a formulated product is listed in the formula, name its basic manufacturer and give its EPA Registration No., if known, in parenthesis following the name of the product. (Also see instruction "C" above.) The trade name and manufacturer of surfactants and other adjuvants (dyes, emulsifiers, solvents, perfumes) must be listed. The complete chemical composition of emulsifiers and surfactants must be listed. Enclose the manufacturer's name in parenthesis following the product listed by trade name. (Also see instruction "C" above.) If a dye or other coloring is used, state the color.
- 12. Enter the percentage by weight of each active and inert ingredient beside the ingredient to which it applies. The percentages by weight for the active ingredients must agree with those appearing in the ingredient statement on the label. The sum of all percentages listed must equal 100 percent.
- 13. Self explanatory.
- 14. Self explanatory.
- 15. Self explanatory.

1. CARD CODE

2
(Col. 2)

2. ACTION CODE

U
(Col. 2)

3. MANUFACTURER

PRODUCT

0359002
(Col. 1-3)

(Same as Card 1)

5. USE CATEGORIES

1	2	3	4	5	6	7	8	9	10
14	19	24	29	34	39	44	49	54	59

1ST CARD

11	12	13	14	15	16	17	18	19	20
64	69	74	79	84	89	94	99	04	09

5. USE CATEGORIES

1	2	3	4	5	6	7	8	9	10
14	19	24	29	34	39	44	49	54	59

2ND CARD

11	12	13	14	15	16	17	18	19	20
64	69	74	79	84	89	94	99	04	09

5. USE CATEGORIES

1	2	3	4	5	6	7	8	9	10
14	19	24	29	34	39	44	49	54	59

3RD CARD

11	12	13	14	15	16	17	18	19	20
64	69	74	79	84	89	94	99	04	09

EPA Hq Form T-46 (10-74) (Reverse)

PRODUCT LABEL CODED INFORMATION (New)
(Use this form to enter New Products)

I- ADD ONLY

1. CARD CODE 1 (Col. 1)	2. ACTION CODE A (Col. 2)	3. MANUFACTURER 035900000002 (Col. 3-8)	4. PRODUCT 035900000002 (Col. 9-13)
5. DATE (MO) (YR) 10 10 (Col. 14-17)	6. TYPE OF PESTICIDE (Col. 18-33)		7. FORM 33 (Col. 36-39)
		8. CAT TOX (Col. 40)	

II

1. CARD CODE 2 (Col. 1)	2. ACTION CODE 1 (Col. 2)	3. MANUFACTURER 035900000002 (Col. 3-8)	4. PRODUCT 035900000002 (Col. 9-13)
(Same as Card 1)			

5., 6. INGREDIENTS AND PERCENTAGES

1ST CARD	14 072501 19	20 010500 25	26 [REDACTED] 31	32 [REDACTED] 37	38 [REDACTED] 43	44 [REDACTED] 49
	50 [REDACTED] 55	56 [REDACTED] 61	62 [REDACTED] 67	68 [REDACTED] 73		

5., 6. INGREDIENTS AND PERCENTAGES

2ND CARD	14 [REDACTED] 19	20 [REDACTED] 25	26 [REDACTED] 31	32 [REDACTED] 37	38 [REDACTED] 43	44 [REDACTED] 49
	50 [REDACTED] 55	56 [REDACTED] 61	62 [REDACTED] 67	68 [REDACTED] 73		

5., 6. INGREDIENTS AND PERCENTAGES

3RD CARD	14 [REDACTED] 19	20 [REDACTED] 25	26 [REDACTED] 31	32 [REDACTED] 37	38 [REDACTED] 43	44 [REDACTED] 49
	50 [REDACTED] 55	56 [REDACTED] 61	62 [REDACTED] 67	68 [REDACTED] 73		

